Medical Policy

Blue Cross Blue Shield Blue Care Network of Michigan

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***Current Policy Effective Date: 1/1/25**
(See policy history boxes for previous effective dates)

Title: Cryoablation or Cryoneurolysis (e.g., iovera° System) of Peripheral Nerves

Description/Background

Peripheral Nerve Pain

There are many types of peripheral neuropathy, which can be brought on by diabetes, genetic predisposition (hereditary causes), exposure to toxic chemicals, alcoholism, malnutrition, inflammation (infectious or autoimmune), injury and nerve compression, and by taking certain medications such as those used to treat cancer and HIV/AIDS. When the cause of a person's peripheral neuropathy remains unknown, it is called 'idiopathic.'

Cryoneurolysis of nerves has been proposed as treatments for several different types of pain. This review evaluates the application of cryoneurolysis in peripheral sites distant from the spine.

Diagnosis

The symptoms of peripheral neuropathy are highly variable. A thorough neurological examination is required to sort out the cause of the symptoms and involves taking an extensive medical history. In addition, tests are usually performed (e.g., nerve conduction velocity, electromyography, nerve biopsy) to identify the cause of the neuropathy as well as the extent and type of nerve damage.

Treatments

Neuropathic pain is often difficult to control. Mild pain may sometimes be alleviated by over-the-counter analgesics such as nonsteroidal anti-inflammatory drugs (NSAIDs) or prescribed medications such as antidepressants, anticonvulsant medications or narcotic agents. Topically administered medications are another option for neuropathic pain. Two agents are topical lidocaine, an anesthetic agent, and capsaicin, a substance found in hot peppers that modifies peripheral pain receptors.

Surgical intervention may be considered for some types of neuropathies. Injuries to a single nerve caused by focal compression may respond well to surgery that releases the nerve from

the tissues compressing it. Some surgical procedures reduce pain by destroying the nerve (e.g., thermal [heat or cold], electrical or chemical); this approach may be appropriate only for pain caused by a single nerve and when other forms of treatment have failed to provide relief. Peripheral neuropathies that involve more diffuse nerve damage, such as diabetic neuropathy, are not amenable to surgical intervention.

Cryoneurolysis
Cryoneurolysis is an alternative analgesic modality that utilizes extremely cold temperatures to reversibly ablate peripheral nerves. This technique has predominantly been used to treat chronic pain, although percutaneous probes, ultrasound guidance, and the recent development of a handheld cryoneurolysis device now, enable a wider range of clinical applications. Cryoneurolysis has been used for treatment of lower back pain, neck pain, neuromas, and intercostal neuralgia. It is being investigated as a possible treatment for peripheral neuropathies, neuromas as well as pain and symptoms of knee osteoarthritis and thoracotomy.

Cryoneurolysis is being investigated to alleviate pain in knee osteoarthritis and to manage pain following total knee arthroplasty. Temperatures of -20° to -100°C applied to a nerve cause Wallerian (anterograde axonal) degeneration, with disruption of nerve structure and conduction but maintenance of the perineural and epineural elements of the nerve bundle. Wallerian degeneration allows complete regeneration and recovery of nerve function in about 3 to 5 months.

Chronic Headaches
Numerous treatments for headaches (e.g. migraine, cluster headaches, tension type headaches and cervicogenic headache), occipital neuralgia and persistent idiopathic facial pain (PIFP) (atypical facial pain) have been proposed, with varying levels success. The consensus on standard treatment does not exist, because of the variability in patient selection and clinical outcomes. Pharmacological treatment with oral analgesics, anti-inflammatory medications, tricyclic antidepressants, and anticonvulsant medications have been used alone or in combination with other treatment modalities. Other treatment modalities suggested are: the use of cervical collar during the acute phase; physical therapy with stretching and strengthening exercises; postural training; relaxation exercises; transcutaneous nerve stimulation (TENS); and manual therapy including spinal manipulation and spinal mobilization.

Pharmacological and alternative treatment modalities are not effective for some individuals, and therefore, other treatment methods have been proposed, such as cryoneurolysis (cryoablation, cryotherapy or cryoanalgesia), to attempt to denervate the occipital and/or upper cervical nerve(s) for pain relief.

The iovera° System
The iovera treatment is powered by the Focused Cold Therapy delivery system, a handheld device which harnesses the unique properties of cryotherapy to target peripheral nerves and block pain. Highly pressurized liquid nitrous oxide travels through the handpiece to the closed end needles of the Smart Tip, where it undergoes a phase change and becomes very cold. This phase change forms a precise cold zone in the tissue causing a temporary nerve block.

Regulatory Status

Although cryoablation equipment (e.g., IceRod CX cryoablation probe, IceEDGE 2.4, Visual-ICE™) have received U.S. Food and Drug Administration (FDA) 510(k) marketing clearance, none appear to be specifically indicated for treatment of peripheral nerve pain.

In 2013, the Cryo-Touch IV (iovera°; Pacira formerly Myoscience) was cleared for marketing by FDA through the 510(k) process (K123516). Predicate devices were the Cryo-Touch II (K102021) and Cryo-Touch III (K120415).

In 2014, the iovera system Pacira (formerly Myoscience, Inc) received 510K clearance from the U.S. Food and Drug Administration (FDA). It is cleared to be used to destroy tissue during surgical procedures by applying freezing cold. It can also be used to produce lesions in peripheral nervous tissue by application of cold to selected site for blocking of pain. The iovera device is not indicated for the treatment of central nervous system tissue.

Medical Policy Statement

Cryoablation for the treatment of peripheral neuropathy is **experimental/investigational**. It has not been scientifically demonstrated to improve patient clinical outcomes.

Cryoneurolysis of peripheral nerves to treat pain associated with knee osteoarthritis or total knee arthroplasty is **experimental/investigational.** It has not been scientifically demonstrated to improve patient clinical outcomes.

Cryoneurolysis of peripheral nerves to treat pain associated with cervicogenic headache is **experimental/investigational.** It has not been scientifically demonstrated to improve patient clinical outcomes.

Cryoablation/cryoneurolysis of peripheral nerves to treat pain is **experimental/investigational** in all other conditions with the exception of facet joint pain. It has not been scientifically demonstrated to improve patient clinical outcomes.

Inclusionary and Exclusionary Guidelines

N/A

CPT/HCPCS Level II Codes *(Note: The inclusion of a code in this list is not a guarantee of coverage. Please refer to the medical policy statement to determine the status of a given procedure.)*

Established codes:

N/A

Other codes (investigational, not medically necessary, etc.):

0440T 0441T 0442T 64624 64640

Rationale

Peripheral Neuropathy

Yoon et al (2016) evaluated the safety and efficacy of cryoneurolysis in patients with refractory peripheral neuropathic pain.[1] Twenty-two patients referred for cryoneurolysis of refractory peripheral neuropathy were recruited prospectively from July 2011 to July 2013. The mean patient age was 49.5 years, and 41% of patients were female. Ultrasound imaging of the involved nerves was used for guidance. Percutaneous ablations were performed with a PerCryo 17R device. Pain levels were recorded on a visual analog scale (scores 0-10) before and at 1, 3, 6, 9, and 12 months after the procedure, and complications were documented. Mean pain levels were 8.3 ± 1.9 before intervention and 2.3 ± 2.5 at 1 month, 3.2 ± 2.5 at 3 months, 4.7 ± 2.7 at 6 months, and 5.1 ± 3.7 at 12 months afterward. A Wilcoxon rank-sum test was performed and showed a statically significant decrease between pre- and post-procedural pain scores. There were no complications from the procedures. The authors concluded that cryoneurolysis caused a decrease in self-reported pain scores in patients with chronic refractory neuropathic pain, with moderately long-term relief.

Peripheral Neuromas

Friedman et al (2012) postulated that cryotherapy would have less adverse events than other methods of nerve ablation.[2] A retrospective case series review was performed in patients who had undergone sonographically guided cryoneurolysis for Morton neuromas, postsurgical and posttraumatic neuromas, and idiopathic neuralgia. Fifteen of 20 patients had a positive response to cryoneurolysis, as did 2 of 4 patients with borderline symptoms for chronic regional pain syndrome.

A prospective study testing the efficacy of cryosurgery on lower extremity neuromas was Performed by Caporusso et al (2002).[3] Thirty-one neuromas in 20 patients were percutaneously denervated using a Westco Neurostat-III cryoneedle. All patients were surgical candidates who had failed prior conservative treatment. Patient evaluation consisted of a 10-point visual analog scale (VAS) that was administered pre- and postoperatively. Periodic evaluation with the VAS and patient satisfaction was conducted for a 1-year period following the procedure. Immediately after the procedure, all patients reported complete relief of pain and were permitted to return to full activity. Two weeks after the index procedure, patients were categorized into one of three groups: those who remained completely pain free (38.7%), those who had reduced pain (45.2%), and those who had reverted to preprocedure pain levels (16.1%). The pain score of those patients who had reduced pain decreased from a mean of 8.5+/-0.4 preprocedure to 3.5+/-0.4 ($p < .002$). All five patients with no improvement had previous local neurectomies. Even though fewer than 40% of the patients had complete pain relief, an overwhelming 90% stated they would have the procedure performed again. Cryogenic neuroablation appears to be a viable treatment option for patients with lower extremity neuromas.

According to Lewin-Kowalik et al (2006) painful neuroma is a common sequela of peripheral nerve injury which is usually resistant to pharmacologic treatment and requires surgical intervention.[4] The widely accepted methods of neuroma management prevent regrowth of

nerve fibers, thus precluding any functional repair. The present study reviews the currently used methods and experimental approaches to prevent and cure neuromas developing after peripheral nerve injury. The main recommendations are as follows. Special care should be taken to minimize scar formation when operating on peripheral nerves. The laser or scissors transection methods should be used to cut the nerve rather than electrocoagulation or cryoneurolysis. Direct nerve reconstruction, or, if a gap occurs, nerve grafting, should be performed immediately after nerve injury. Surgical resection of recurrent neuroma followed by implantation of the nerve into the muscle or capping the nerve stump with epineural graft appears to be an effective method of prevention.

Post-Thoracotomy/Intercostal Pain

Sepsas et al (2013) studied the effects of cryoanalgesia, combined with intravenous patient-controlled analgesia (IVPCA) against IVPCA alone during the four days following surgery.[5] Fifty patients were randomized into two groups: an IVPCA group (n = 25) and an IVPCA-cryo group (n = 25). Subjective pain intensity was assessed on a verbal analogue scale at rest and during coughing. The intensity and the incidence of post thoracotomy pain, numbness, epigastric distension and/or back pain, the analgesic requirements, as well as the blood gas values and respiratory function tests were evaluated up to the second postoperative (postop) month. Haemodynamic data and episodes of nausea and/or vomiting were recorded over the four postop days. In the cryo group there was a statistically significant improvement in postop pain scores (P = 10(-4)), reduction in consumption of morphine (P = 10(-4)) and other analgesics (P = 10(-4)), optimization (less acidosis) of the pH values of blood gases (P < 0.015 over 72 hours postop and P < 0.03 on the first and second postop months), increase in systolic blood pressure (P < 0.05 over 96 hours postop), reduction in heart rate (P < 0.05 over 96 hours postop), increase in values of FEV1 (P < 0.02) and FVC (P < 0.05) at the first and second postop months, reduction in the incidence of nausea (0.05 < P < 0.1 over 18 hours postop), numbness, epigastric distension and back pain (P < 0.05 at days 5, 6, 7, 14, 30 and 60 following surgery). The authors concluded that cryoanalgesia might be considered safe, inexpensive, and long-term form of post-thoracotomy pain relief. Cryoanalgesia effectively restores FEV1 values at the second postop month.

Khanbhai et al (2014) identified and reviewed twelve articles that examined cryoanalgesia as a treatment for pain relief post thoracotomy surgery.[6] Half of the articles reviewed failed to demonstrate superiority of cryoanalgesia over other pain relief methods; however, additional opiate requirements were reduced in patients receiving cryoanalgesia. Change in lung function, postoperatively was equivocal. Cryoanalgesia potentiated the incidence of postoperative neuropathic pain. Further analysis of the source of cryoanalgesia, duration, temperature obtained and extent of blockade revealed numerous discrepancies. Three studies utilized CO2 as the source of cryoanalgesia and four used nitrous oxide, but at differing temperatures and duration. Five studies did not reveal the source of cryoanalgesia. The number of intercostal nerves anaesthetized in each study varied. Seven articles anaesthetized three intercostal nerves; three articles used five intercostal nerves, one article used four intercostal nerves and one used one intercostal nerve at the thoracotomy site. Thoracotomy closure and site of area of chest drain insertion may have a role in postoperative pain; but only one article explained method of closure, and two articles mentioned placement of chest drain through blocked dermatomes. No causal inferences can be made by the above results as they are not directly comparable due to confounding variables between studies. The authors conclude that the evidence does not support the use of cryoanalgesia alone as an effective method for relieving post-thoracotomy pain.

Cryoneurolysis for Total Knee Arthroplasty/Osteoarthritis Pain

Dasa et al (2016) hypothesized that a pre-operative block 5 days prior to surgery would decrease TKA postoperative pain and lead to improved patient outcomes.[7] Forty-eight patients were included in this retrospective chart review. Twenty-four patients undergoing TKA prior to March 31, 2014 comprised the control group. The second 24 patients undergoing TKA following percutaneous cryoneurolysis treatment comprised the treated group. Subjects in the treated group received a cryoneurolysis treatment to the infrapatellar branch of the saphenous nerve (ISN) and the anterior femoral cutaneous nerve (AFCN) five days prior to TKA; Subjects in the control group received standard pre-operative care. Institutional Review Board approval was obtained for this retrospective study. Patient reported outcome measures were collected using the KOOS, Oxford Knee Score, SF12 and PROMIS scales at baseline (pre cryoneurolysis), and at the 2, 6 and 12 weeks postoperative visit. Secondary measures included hospital length of stay and number of narcotic pain medication requested by patients at the 2, 6 and 12 week postoperative visits. Discharge criteria included the ability to walk 50 feet with a walker or crutches, to get in and out of bed and on and off a toilet independently, and pain control with oral medications.

According to the authors, the results demonstrate that though the two groups show similar average functional and pain scores at each of the follow-up time points the cryoneurolysis treated group required half of the narcotics to achieve the same results as the control group. Because cryoneurolysis does not introduce any local or systemic medications, it can prevent both intra- and postoperative pain while avoiding typical side effects. Further, given that, the effects of this cryoneurolysis treatment last for a month or more this may allow patients to reduce their medication dependence prior to TKA. In addition to benefits for the patient, the statistically significant reduction in hospital length of stay because of the cryoneurolysis treatment protocol could reduce acute care facility costs as well as the potential for nosocomial infections. Further, the reduction in narcotics prescribed could result in reduced costs due to a reduction in narcotics related side effects. Limitations to this study include the historical group as a control and the lack of randomization.

Radnovich et al (2017) evaluated the efficacy and safety of cryoneurolysis for reduction of pain and symptoms associated with knee osteoarthritis.[8] In a randomized, double-blind, sham-controlled, multicenter trial with a 6-month follow-up in patients with mild-to-moderate knee OA. The intent-to-treat (ITT) population consisted of 180 patients (n = 121 active treatment, n = 59 sham treatment). Compared with sham-treated individuals, cryoneurolysis resulted in a greater decrease in WOMAC pain score, WOMAC total score, and VAS score at 30 days. The cryoneurolysis group also had better WOMAC total scores at 90 days but not at 60 days. Improvements in VAS scores did not differ significantly between active and sham treatment groups at 60 and 90 days.

Technical Issues

Several technical issues have yet to be resolved, including the optimal number of applications for each nerve, the duration of treatment, and the duration of thawing before moving the cannula. The most effective method for determining the location of the probe (e.g., ultrasound or using anatomic landmarks) also needs to be established.

Chronic Headaches

Chong et al (2015) reported on a retrospective evaluation on the efficacy and safety of cryoablation for the treatment of occipital neuralgia (ON) in an academic university based pain management center.[15] All patients received local anesthetic injections of ON. Patients with greater than or equal to 50% relief and less than 2 week duration of relief were treated with cryoablation. Thirty eight patients were included. Of the 38 patients 20 were treated for unilateral greater occipital neuralgia (ON), 10 for unilateral greater and lesser ON, and 8 for bilateral greater ON. There were 10 men and 28 women, with an average age of 45.2 years and 51.1 years respectively. The average relief for all local anesthetic injections was 71.2%, 58.3% for patients who reported 50-74% relief (Group 1) and 82.75% for patients who reported greater than 75% relief (Group 2). The average improvement of pain relief with cryoablation was 57.9% with an average duration of 6.1 months overall. Group 1 reported an average of 45.2% relief for an average of 4.1 months with cryoablation. In comparison, Group 2 reported an average of 70.5% relief for 8.1 months. The percentage of relief (P=0.007) and duration of relief (P=0.0006) was significantly improved in those reporting at least 75% relief of pain with local anesthetic injections (Group 2 vs. Group 1). Though no significance in improvement from cryoablation was found in men, significance was seen in women with at least 75% benefit with local anesthetic injections in terms of duration (P=0.03) and percentage (P=0.001) of pain relief with cryoablation. The average pain score prior to cryoablation was 8 (0-10 visual analog scale, VAS), this improved to 4.2, improvement of 3.8 following cryoablation at 6 months (P=0.03). Of the 38 patients, 3 (7.8%) adverse effects were seen. Two patients reported post procedure neuritis and one was monitored for procedure related hematoma. Study limitations included the retrospective nature of the study. Additionally, only the percentage relief, pain score and duration of relief were collected. This study was limited by design and lack of long term outcomes.

Stogicza et al (2019) described an ultrasound (US) guided cryoneuroablation technique of the proximal greater occipital nerve (GON).[16] The authors provide a description of the procedure based on experience in the authors' clinic. With the patient in the prone position, the US probe is placed parallel to the inferior oblique capitis muscle (IOCM). The GON is seen on top of the IOCM; a midline 2-mm incision allows access to the bilateral GONs with a single skin entry. Using an in-plane approach, the cryo probe is advanced to the nerve in a medial-to-lateral direction, with constant US visualization, staying far away from the spinal cord and vertebral artery, which increases safety. The authors concluded that based on anecdotal evidence, cryoneuroablation of the GON can be performed safely, however a formal study is warranted.

Grigsby et al (2021) recently published the results of a pilot study evaluating the safety and efficacy of percutaneous cryoneurolysis for the treatment of occipital neuralgia (ON) related pain. [17] A total of 26 patients (mean age 49.1 years) participated in this prospective, multicenter, nonrandomized cohort study which assessed the degree and duration of the effect of cryotherapy for pain reduction in individuals with either unilateral or bilateral ON. Results were measured by assessing level of pain due to ON based on an 11-point numeric scale at baseline and day 7. Ongoing treatment effect was measured at day 30 and day 56 by patient inquiry with “effect”, “no effect” or “no longer effective” as possible responses. Overall, a clinically important improvement of symptoms (≥ 2 points in numeric rating scale) was reported by 64% of participants at day 7, with similar results lasting through day 30. Pain reduction continued for 50% of participants at day 30 and for 35% of participants at day 56. No adverse events were reported. The authors concluded that cryoneurolysis provided substantial relief from pain related to ON ≤ 30 days after treatment with no safety issues, however several

limitations to this study were noted. The study was uncontrolled and unblinded in design, so cryoneurolysis was unable to be compared with other ON treatments, and the lack of a control group introduced potential for bias. In addition, the study had a very small population size and did not include outcome measures assessing impact of treatment with cryoneurolysis on quality of life. The researchers recommend more rigorous clinical trials including a larger population, comparator group(s) and better characterization of participants at baseline to establish efficacy and safety.

iovera° System

A search of the peer-reviewed literature located a small body of literature specifically addressing the iovera° System for use in the management of knee pain. Dasa et al (2016) reported on postoperative outcomes in total knee arthroplasty patients pretreated with cryoneurolysis 5 days prior to surgery. Radnovich et al (2017) reported on the durability of pain relief following cryoneurolysis for osteoarthritis of the knee, however, this study did not involve surgical patients. Bellini and Barbieri (2015) reported on pain relief following percutaneous cryoanalgesia in 18 patients with a variety of orthopedic maladies including facet, sacroiliac, and knee pain. It could not be determined how many of the 18 patients presented with knee issues. No studies described the use of cryoneurolysis or iovera° in the postoperative setting.

SUMMARY OF EVIDENCE

There is very limited peer-reviewed literature pertaining to cryoablation for peripheral neuropathy. The body of evidence is heterogeneous regarding cryoablation of specific nerves, protocols used, prior conservative management, and length of follow-up. Although it appears that some patients reported satisfaction with the procedure in both studies, it is not clear whether daily functioning improved after the procedure. The weakness in the body of evidence precludes conclusions on the efficacy of cryoablation for peripheral neuropathies.

For individuals who have knee osteoarthritis or total knee arthroplasty who receive cryoneurolysis of peripheral nerves, the evidence includes an RCT with 180 patients and a retrospective comparative study. Cryoneurolysis in patients with knee osteoarthritis resulted in some improvement at 30 days compared with sham-treated controls. However, subsequent measurements showed no significant benefit of cryoneurolysis at 60 or 90 days. Perioperative cryoneurolysis was shown in a retrospective comparison to reduce the length of stay and opioid use in patients undergoing total knee arthroplasty. These results need to be confirmed in an RCT. Several technical issues including the optimal number of applications for each nerve, the duration of treatment, and the duration of thawing before moving the cannula have not been resolved. The evidence is insufficient to determine the effects of the technology on health outcomes.

For individuals who suffer with chronic headaches the evidence is limited to a retrospective study. No randomized controlled trials were found. The evidence is insufficient to establish the safety and efficacy of this technique in the treatment of pain associated with occipital neuralgia and/or chronic headaches (including but not limited to cervicogenic headache, migraines, cluster headaches, tension headaches). Further larger well-designed studies with longer periods of follow-up are needed to evaluate the use of cryoneurolysis (cryoablation, cryotherapy or cryoanalgesia) for these conditions and to identify which patients would benefit from this procedure. The evidence is insufficient to determine the effects of this technology on net health outcomes.

Ongoing and Unpublished Clinical Trials

Currently unpublished trial(s) 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			
NCT03774121	Cryoneurolysis for the management of chronic pain in patients with knee osteoarthritis	90	Mar 2023
NCT03578237	Cryoanalgesia to Prevent Acute and Chronic Pain Following Surgery: A Randomized, Double-Masked, Sham-Controlled Study	380	Jul 2023
NCT03567187	Cryoneurolysis for Improvements in Pain, ADL and QOL in Patients With Ankle Osteoarthritis	40	Mar 2021
NCT04191031	Study to Evaluate Iovera®° in Adult Patients Undergoing Total Knee Arthroplasty	200	September 2021
Unpublished			
NCT03429972	Regional cryotherapy in preventing paclitaxel induced peripheral neuropathy in breast cancer patients	51	Jun 2020
NCT03818022	Pain Control With Pre-operative Cryoneurolysis Following TKA	100	Dec 2020 (unknown)
NCT01788410	MRI-guided cryoablation to alleviate pain in head, neck and spine	50	May 2020

NCT: national clinical trial

SUPPLEMENTAL INFORMATION

PRACTICE GUIDELINES AND POSITION STATEMENTS

Association of Extremity Nerve Surgeons (AENS)[9]

The AENS developed clinical practice guidelines in 2014 on peripheral nerve surgery. They state, “Cryoablation (cryotherapy) should be used with extreme caution, as the amount of literature in the lower extremity is limited.”

American Academy of Neurology (AAN)[10]

The AAN, along with the American Association of Neuromuscular and Electrodiagnostic Medicine and the American Academy of Physical Medicine and Rehabilitation, developed guidelines on oral and topical treatment of painful diabetic polyneuropathy (2021). The guidelines recommend pharmacotherapy for the treatment of peripheral nerve pain. There is no mention of cryoneurolysis as a therapy for neuropathy.

In 2012, the AAN issued an evidence based guideline update on NSAIDS and other complementary treatments for episodic migraine prevention in adults which does not mention ablative treatments.

National Institute for Health and Clinical Excellence (NICE)[11]

The NICE has issues guidelines (2020) on neuropathic pain, which state, “a choice of amitriptyline, duloxetine, gabapentin or pregabalin is the choices for initial treatment for neuropathic pain. If the initial treatment is not effective or is not tolerated, offer one of the

remaining 3 drugs, and consider switching again if the second and third drugs are tried are also not effective or tolerated." There is no mention of cryoneurolysis as a therapy for peripheral nerve pain or chronic headache pain.

Government Regulations

National:

There is no national coverage determination (NCD) for cryoablation of peripheral nerves

Local:

There is no local coverage determination (NCD) for cryoablation of peripheral nerves. However, there is an LCD (L35490), Category III Codes effective for services on or after 04/27/23 that address coverage of certain codes. Codes 0440T-0442T are not on the list of covered codes.[12]

(The above Medicare information is current as of the review date for this policy. However, the coverage issues and policies maintained by the Centers for Medicare & Medicare Services [CMS, formerly HCFA] are updated and/or revised periodically. Therefore, the most current CMS information may not be contained in this document. For the most current information, the reader should contact an official Medicare source.)

Related Policies

- Cryoablation of Miscellaneous Solid Tumors other than Liver, Prostate, or Dermatologic Tumors
- Cryoablation of Liver Tumors
- Ablation of Peripheral nerves to Treat Pain including Coolief Cooled RF and Iovera System

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19. HAYES Evolving Evidence Review. The iovera° (Pacira BioSciences Inc.) System for Pain Associated with Total Knee Arthroplasty. Lansdale, PA: HAYES, Inc., published May 24, 2023.
20. HAYES Evolving Evidence Review. The iovera° (Pacira Biosciences Inc.) System for Knee Osteoarthritis. Lansdale, PA: HAYES, Inc., published Dec 20, 2022.

The articles reviewed in this research include those obtained in an Internet based literature search for relevant medical references through August 2023, the date the research was completed.

Joint BCBSM/BCN Medical Policy History

Policy Effective Date	BCBSM Signature Date	BCN Signature Date	Comments
1/1/18	10/19/17	10/19/17	Joint policy established
1/1/19	10/16/18	10/16/18	Routine policy maintenance. Added iovera° System to the policy. No change in policy status.
1/1/20	10/15/19		Added exclusions to inclusion/exclusion section for clarification, added chronic headaches to exclusion section, background section and rationale section, two references added # 16 & 17. Added language to the summary section addressing chronic headache
1/1/21	10/20/20		Routine policy maintenance. No change in policy status.
1/1/22	10/19/21		Routine policy maintenance. No change in policy status.
1/1/23	10/18/22		Routine policy maintenance. No change in policy status. Updated MPS: Added Cryoneurolysis of peripheral nerves to treat pain associated with knee osteoarthritis or total knee arthroplasty is considered experimental/investigational. It has not been scientifically demonstrated to improve patient clinical outcomes. Title updated to Cryoablation or Cryoneurolysis (e.g., iovera° System) of Peripheral Nerves (ky) Post JUMP changes: Added 64624 and 64640 to the policy. Updated MPS: Removed (i.e., cryoneurolysis, cryoanalgesia) from the below sentence.

			Cryoablation (i.e., cryoneurolysis, cryoanalgesia) for the treatment of peripheral neuropathy is experimental/investigational. It has not been scientifically demonstrated to improve patient clinical outcomes. Removed the below sentence. Cryoablation treatment for peripheral neuropathy includes, but is not limited to, the following conditions: o Peripheral neuropathy brought on by diabetes, genetic predisposition (hereditary causes), exposure to toxic chemicals, alcoholism, malnutrition, inflammation (infectious or autoimmune), injury and nerve compression, or by taking certain medications such as those used to treat cancer and HIV/AIDS o Peripheral neuromas o Post-Thoracotomy/Intercostal Pain o Total Knee Arthroplasty/Osteoarthritis Pain o Chronic headaches (e.g., migraine, tension, cluster, cervicogenic, occipital neuralgia) Added the below to the MPS. o Cryoneurolysis of peripheral nerves to treat pain associated with knee osteoarthritis or total knee arthroplasty is experimental/investigational. It has not been scientifically demonstrated to improve patient clinical outcomes. o Cryoneurolysis of peripheral nerves to treat pain associated with cervicogenic headache is experimental/investigational. It has not been scientifically demonstrated to improve patient clinical outcomes. o Cryoablation/cryoneurolysis of peripheral nerves to treat pain is experimental/investigational in all other conditions with the exception of facet joint pain. It has not been

			scientifically demonstrated to improve patient clinical outcomes. (ky)
1/1/24	10/17/23		Routine policy maintenance. No change in policy status. Vendor: TurningPoint. (ky)
1/1/25	10/15/24		Routine policy maintenance. No change in policy status. Vendor: TurningPoint. Combined JUMP policy Cryoablation or Cryoneurolysis (e.g., iovera° System) of Peripheral Nerves with the JUMP policy Radiofrequency Ablation of Peripheral Nerves to Treat Pain including Coolief Cooled RF. The new policy title is now called Ablation of Peripheral Nerves to Treat Pain including Coolief Cooled RF and Iovera System (ky)

Next Review Date: Policy replaced, no further review.

Pre-Consolidation Medical Policy History

Original Policy Date	Comments
BCN:	Revised:
BCBSM:	Revised:

BLUE CARE NETWORK BENEFIT COVERAGE
POLICY: CRYOABLATION OR CRYONEUROLYSIS (E.G., IOVERA° SYSTEM) OF PERIPHERAL NERVES

I. Coverage Determination:

Commercial HMO (includes Self-Funded groups unless otherwise specified)	Not covered
BCNA (Medicare Advantage)	See government section
BCN65 (Medicare Complementary)	Coinsurance covered if primary Medicare covers the service.

II. Administrative Guidelines:

- The member's contract must be active at the time the service is rendered.
- Coverage is based on each member's certificate and is not guaranteed. Please consult the individual member's certificate for details. Additional information regarding coverage or benefits may also be obtained through customer or provider inquiry services at BCN.
- The service must be authorized by the member's PCP except for Self-Referral Option (SRO) members seeking Tier 2 coverage.
- Services must be performed by a BCN-contracted provider, if available, except for Self-Referral Option (SRO) members seeking Tier 2 coverage.
- Payment is based on BCN payment rules, individual certificate and certificate riders.
- Appropriate copayments will apply. Refer to certificate and applicable riders for detailed information.
- CPT - HCPCS codes are used for descriptive purposes only and are not a guarantee of coverage.