

## Medicare Advantage Medical Policy



### MA: ALBATION OF PERIPHERAL NERVES TO TREAT PAIN

EFFECTIVE 01/01/2024

#### Description

Radiofrequency ablation (RFA) and cryoneurolysis of nerves have been proposed as treatment for several different types of pain. RFA has been used to treat a number of clinical pain syndromes such as trigeminal neuralgia as well as cervical and lumbar pain. This review evaluates the application of RFA and cryoneurolysis in peripheral sites distant from spine.

#### Policy

I. Radiofrequency ablation or cryoneurolysis of peripheral nerves to treat pain associated with knee osteoarthritis, total knee arthroplasty, plantar fasciitis, occipital neuralgia, or cervicogenic headache is considered **investigational**.

II. Intercostal nerve cryoablation during pectus excavatum surgery, including Nuss procedure, for pain control is considered **investigational**.

III. Ablation of peripheral nerves to treat pain is considered **investigational** in all other conditions, with the exception of facet joint pain.

#### Background

##### Knee Osteoarthritis

Knee OA is common, costly, and often the cause of substantial disability. Among U.S. adults, the most common causes of disability are arthritis and rheumatic disorders.

##### Plantar Fasciitis

Plantar fasciitis is a common cause of foot pain in adults, characterized by deep pain in the plantar aspect of the heel, particularly on arising from bed. While the pain may subside with activity, in some patients the pain persists and can impede activities of daily living. On physical examination, firm pressure will elicit a tender spot over the medial tubercle of the calcaneus. The exact etiology of plantar fasciitis is unclear, although a repetitive injury is suspected. Heel spurs are a common associated finding, although it has never been proven that heel spurs cause the pain. Asymptomatic heel spurs can be found in up to 10% of the population.

##### Occipital Neuralgia

Occipital neuralgia is a specific type of headache that is located on one side of the upper neck, back of the head, and behind the ears, and sometimes extending to the scalp, forehead, and behind the eyes. The pain, which may be piercing, throbbing, or electric-shock-like, follows the course of the greater and lesser occipital nerves. Occipital neuralgia is believed to occur due to pressure or irritation to the occipital nerves, which may result from injury, entrapment by tight muscles, or inflammation.

## **Cervicogenic Headache**

Cervicogenic headache is characterized as a headache that is secondary to a disorder of the cervical spine. The existence of cervicogenic headache as a distinct clinical disorder, and its underlying pathophysiology and treatment remain controversial.

## **Nerve Radiofrequency Ablation**

Nerve RFA is a minimally invasive method that involves the use of heat and coagulation necrosis to destroy tissue. A needle electrode is inserted through the skin and into the tissue to be ablated. A high-frequency electrical current is applied to the target tissue and a small sphere of tissue is coagulated around the needle by the heat generated. It is theorized that the thermal lesioning of the nerve destroys peripheral sensory nerve endings, resulting in the alleviation of pain. Cooled radiofrequency (RF) treatment is a variation of nerve RFA using a water-cooled probe that applies more energy at the desired location without excessive heat diffusing beyond the area, causing less tissue damage away from the nerve.

RFA is also distinguished from pulsed RF treatment, which has been investigated for different types of pain. The mechanism of action of pulsed RF treatment is uncertain but it is thought not to destroy the nerve.

For the indications assessed in this evidence review, nerve RFA should be distinguished from RF energy applied to areas other than the nerve to cause tissue damage.

## **Cryoneurolysis**

Cryoneurolysis is being investigated to alleviate pain in knee OA and to manage pain following total knee arthroplasty as well as for intracostal surgery such as pectus excavatum surgery. Temperatures of -20° to -100°C applied to a nerve cause Wallerian (anterograde axonal) degeneration, with disruption of nerve structure and conduction but the maintenance of the perineural and epineural elements of the nerve bundle. Wallerian degeneration allows complete regeneration and recovery of nerve function in about three to five months. The Iovera° cryoablation system is a portable handheld device that applies percutaneous and targeted delivery of cold to superficial peripheral nerves.

## **Regulatory Status**

A number of RF generators and probes have been cleared for marketing by the U.S. Food and Drug Administration (FDA) through the 510(k) process. In 2005, the SInergy® (Kimberly-Clark/Baylis), a water-cooled single-use probe, was cleared by the FDA, listing the Baylis Pain Management Probe as a predicate device. The intended use is with an RF generator to create RF lesions in nervous tissue. FDA product code: GXD.

In 2011, NeuroTherm® NT 2000 (NeuroTherm) was cleared for marketing by the FDA through the 510(k) process. The FDA determined that this device was substantially equivalent to existing devices for use in lesioning neural tissue. Existing predicate devices included the NeuroTherm NT 1000, Stryker Multi-Gen, and Cosman G4 RF Generator.

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

In 2017, the COOLIEF Cooled Radiofrequency Probe (Avanos, previously known as Halyard Health) was cleared for marketing by the FDA through the 510(k) process to be used in conjunction with a radiofrequency generator to create lesions in nervous tissue (K163461). "The device is also indicated for creating radiofrequency lesions of the genicular nerves for the management of moderate to severe knee pain of more than 6 months with conservative therapy, including medication, in patients with radiologically-confirmed osteoarthritis (grade 2-4) and a positive response ( $\geq$  50% reduction in pain) to a diagnostic genicular nerve block." FDA Product Code: GXI

## **Codes**

<b>64624</b>	<b>64640</b>	<b>64999</b>	<b>015D3ZZ</b>	<b>015F3ZZ</b>
<b>015G3ZZ</b>	<b>015H3ZZ</b>			

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