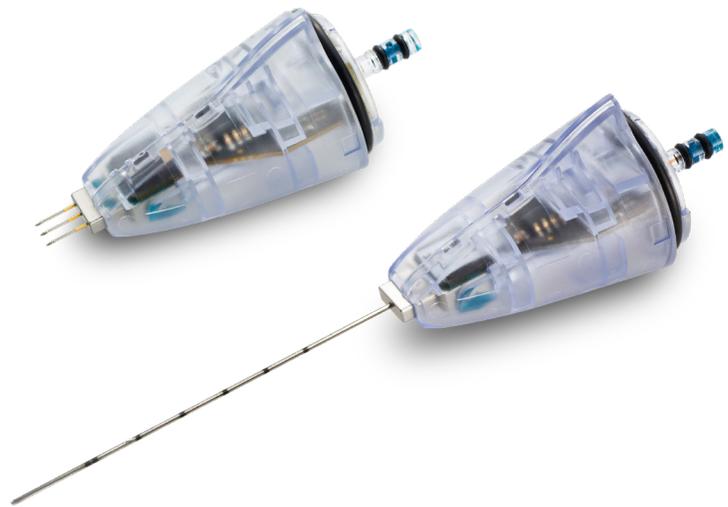


iovera<sup>o</sup>

**iovera<sup>o</sup> CODING &  
REIMBURSEMENT  
CONSIDERATIONS**



*Product shown in actual size*

Myoscience, Inc. is an innovative medical device company committed to making its patented proprietary technology, the iovera<sup>®</sup> System, the standard of care for the treatment of peripheral nerves. To help answer common coding and reimbursement questions about the iovera<sup>®</sup> procedures, the following information is shared for educational and strategic planning purposes. While Myoscience believes this information to be correct, we recognize that coding is the sole responsibility of healthcare providers and is subject to change without notice. As a result, healthcare providers are encouraged to speak regularly with their payers and to become familiar with their policies related to peripheral nerve blocks.

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## Regulatory Clearance

Myoscience received 510K clearance from the U.S. Food and Drug Administration (FDA) for the iovera<sup>®</sup> device on January 10, 2013. It is used to destroy tissue during surgical procedures by applying freezing cold. It can also be used to produce lesions in peripheral nervous tissue by the application of cold to the selected site for the blocking of pain. It is also indicated for the relief of pain and symptoms associated with osteoarthritis of the knee for up to 90 days. The iovera<sup>®</sup> system is not indicated for treatment of central nervous system tissue.

The iovera<sup>®</sup> system's "1x90" Smart Tip configuration (indicating one needle which is 90 mm long) can also facilitate target nerve location by conducting electrical nerve stimulation from a separate nerve stimulator. (K123516, K133453, K142866, K161835, K173763).

## Product Description

The iovera<sup>®</sup> handheld device delivers a controlled dosage of liquid nitrous oxide to the closed-end probes of the Smart Tip, which is then applied to specific targeted nerves. As this highly pressurized liquid travels from the handpiece to the Smart Tip, it undergoes a phase change becoming very cold, drawing in heat energy from

the surrounding tissue and forming a precise zone of cold at the targeted nerve. The gaseous nitrous oxide returns into the handpiece, leaving nothing behind in the body. This precise cold treatment causes a reversible nerve block based on a process called Wallerian degeneration. Pain is relieved as the signal is not able to conduct along the sensory nerves until the axon is regenerated. The nerve axon regenerates at the rate of about 1mm per day, which provides a predictable indicator for restoration of nerve function.

## Clinical Value

Cryoneurolysis has been used clinically for decades to provide temporary pain relief.<sup>1</sup> A large body of clinical work and commercial use over the past 35 years demonstrates relief for patients with various types of pain including, but not limited to, post-herpetic neuralgia,<sup>2-3</sup> neuroma,<sup>4</sup> intractable facial,<sup>5-9</sup> temporomandibular joint,<sup>10</sup> post-thoracotomy,<sup>11</sup> intercostal,<sup>12</sup> and perineal pain.<sup>13</sup> These reports have demonstrated pain relief ranging from a couple of months to a few years.<sup>6,8</sup> Generally, no sedation is used so the patient can assist in identifying the site of pain and the location of the target nerve(s). Because peripheral nerve function is disrupted due to the destruction of the axon and myelin sheath, the desired result is safe and effective, providing pain relief until the nerve(s) regenerates.

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*Information provided by Myoscience in this Coding & Reimbursement Considerations guide is presented for illustrative purposes only and does not constitute coding, reimbursement or legal advice. It is always the provider's responsibility to determine the medical necessity and proper site of service for the procedure, and to submit appropriate codes, charges and modifiers for services rendered. Myoscience recommends that providers consult with payers, reimbursement specialists and/or legal counsel regarding coding, coverage and reimbursement matters to ensure they submit accurate and appropriate claims for services. The information included here is gathered from third-party sources and is subject to change without notice as a result of complex and frequently-changing laws, regulations, rules and policies.*

*Payer coverage and payment policies will vary and should be verified by the provider prior to treatment and billing. The coding options listed within this guide are not intended to be an all-inclusive list of potential codes. We recommend consulting relevant coding manuals and guidance for appropriate coding options. Myoscience does not promote the use of its products outside of their FDA-cleared label.*

## Coding, Coverage and Reimbursement Considerations

Codes provide a uniform language for describing the services performed by healthcare providers. The actual selection of codes depends upon details documented in the patient's medical record. It is the sole responsibility of the healthcare provider to correctly prepare patient claims. The following information is shared solely for informational and educational purposes.

### Physician's Professional Component

Before preparing a claim, healthcare providers are encouraged to review the American Medical Association (AMA)'s instructions for coding "Destruction by Neurolytic Agent (e.g., chemical, thermal, electrical or radiofrequency)" section in CPT 2018. Contingent upon the patient's chief complaint and physical examination, the CPT® code 64640, has been confirmed by the AMA for treatment of peripheral nerves in the knee. This code has also been confirmed to be appropriate for the management of osteoarthritis by the The American Academy of Orthopaedic Surgeons (AAOS) Coding Coverage & Reimbursement Committee.\*

Healthcare providers may ask about thermal destruction of specific peripheral nerves. Providers are encouraged to review AMA's instruction for use of other somatic nerves, such as but not limited to:

CPT® Code	Definition	CMS CY2018 Total Non-Facility RVUs	CMS CY2018 Total Facility RVUs
64600	Destruction by neurolytic agent, trigeminal nerve; supraorbital, infraorbital, mental, or inferior alveolar branch	11.57	6.50
64605	Destruction by neurolytic agent, trigeminal nerve; second and third division branches at foramen ovale	15.53	9.75
64610	Destruction by neurolytic agent, trigeminal nerve; second and third division branches at foramen ovale under radiologic monitoring	21.19	14.15
64620	Destruction by neurolytic agent, intercostal nerve	5.84	4.94
64632	Destruction by neurolytic agent; plantar common digital nerve	2.44	1.98
64633	Destruction by neurolytic agent, paravertebral facet joint nerve(s), with imaging guidance (fluoroscopy or CT); cervical or thoracic, single facet joint	11.92	6.46
64634	Destruction by neurolytic agent, paravertebral facet joint nerve(s), with imaging guidance (fluoroscopy or CT); cervical or thoracic, each additional facet joint	5.36	1.96
64635	Destruction by neurolytic agent, paravertebral facet joint nerve(s), with imaging guidance (fluoroscopy or CT); lumbar or sacral, single facet joint	11.79	6.37
64636	Destruction by neurolytic agent, paravertebral facet joint nerve(s), with imaging guidance (fluoroscopy or CT); lumbar or sacral, each additional facet joint	4.87	1.71
64640	Other peripheral nerve or branch	3.77	2.67

Source: Centers for Medicare and Medicaid Services. Medicare Physician Fee Schedule for CY2018.

Standard off-the-shelf nerve stimulator may be used in applications where precise nerve location is desired.

\*Copies of the correspondence from the AMA and AAOS are available upon request.

## Facility's Technical Component

Facility coding and reimbursement is influenced by the site of service for the primary procedure, patient's chief complaint, associated comorbidities, payer mix and contract terms. Healthcare providers are encouraged to review their payer policies for peripheral nerve blocks and preemptive analgesia related to medically necessary conditions, such as but not limited to:

ICD-10-Diagnosis Codes
M25.5XX Pain in Joint M25.561 Knee pain

CPT	Description	Physician Fee (Non-Facility)	Physician Fee (Facility)	Hospital APC	HOPPS	ASC
64640	Other peripheral nerve or branch	Total RVU=3.77 \$135.72	Total RVU=2.67 \$96.12	#5443 Level III Nerve Injections	\$672.13	\$87.84

Primary citation: CMS 2018 final fee schedules, based on a 2018 Conversion Factor of \$35.9996.

Depending upon a facility's payer contracts, Materials Managers may also want to report the iovera<sup>o</sup> probe with a Level II HCPCS supply code, such as but not limited to A4649 (Surgical supply; miscellaneous) or C2618 (Probe/needle cryoablation).

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