Myoscience, Inc. is an innovative medical device company committed to making its platform technology, the Focused Cold Therapy® delivery system, the standard of care for the treatment of peripheral nerves. Its patented proprietary technology is delivered by the iovera® device. To help answer common coding and reimbursement questions about the iovera® device, 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.

**Regulatory Clearance**

Myoscience received 510K clearance from the U.S. Food and Drug Administration (FDA) for the iovera® device on January 10, 2013. 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 the selected site for blocking of pain. The iovera® device is not indicated for treatment of central nervous system tissue (K123516, K133453, K142866).

**Product Description**

The iovera® 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**

Cryoanalgesia has been used clinically for decades to provide temporary pain relief. 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,2-3 neuroma,4 intractable facial,5-9 temporomandibular joint,10 post-thoracotomy,11 intercostal,12 and perineal pain.13 These reports have demonstrated pain relief ranging from a couple of months to a few years.6,8 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.

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 2016. 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.

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:

<table>
<thead>
<tr>
<th>CPT® Code</th>
<th>Definition</th>
<th>CMS CY2016 Total Non-Facility RVUs</th>
<th>CMS CY2016 Total Facility RVUs</th>
</tr>
</thead>
<tbody>
<tr>
<td>64600</td>
<td>Destruction by neurolytic agent, trigeminal nerve; supraorbital, infraorbital, mental, or inferior alveolar branch</td>
<td>11.14</td>
<td>6.32</td>
</tr>
<tr>
<td>64605</td>
<td>Destruction by neurolytic agent, trigeminal nerve; second and third division branches at foramen ovale</td>
<td>21.44</td>
<td>11.94</td>
</tr>
<tr>
<td>64610</td>
<td>Destruction by neurolytic agent, trigeminal nerve; second and third division branches at foramen ovale under radiologic monitoring</td>
<td>21.35</td>
<td>14.23</td>
</tr>
<tr>
<td>64620</td>
<td>Destruction by neurolytic agent, intercostal nerve</td>
<td>5.82</td>
<td>4.93</td>
</tr>
<tr>
<td>64632</td>
<td>Destruction by neurolytic agent; plantar common digital nerve</td>
<td>2.43</td>
<td>1.97</td>
</tr>
<tr>
<td>64633</td>
<td>Destruction by neurolytic agent, paravertebral facet joint nerve(s), with imaging guidance (fluoroscopy or CT); cervical or thoracic, single facet joint</td>
<td>12.06</td>
<td>6.54</td>
</tr>
<tr>
<td>64634</td>
<td>Destruction by neurolytic agent, paravertebral facet joint nerve(s), with imaging guidance (fluoroscopy or CT); cervical or thoracic, each additional facet joint</td>
<td>5.42</td>
<td>1.98</td>
</tr>
<tr>
<td>64635</td>
<td>Destruction by neurolytic agent, paravertebral facet joint nerve(s), with imaging guidance (fluoroscopy or CT); lumbar or sacral, single facet joint</td>
<td>11.92</td>
<td>6.45</td>
</tr>
<tr>
<td>64636</td>
<td>Destruction by neurolytic agent, paravertebral facet joint nerve(s), with imaging guidance (fluoroscopy or CT); lumbar or sacral, each additional facet joint</td>
<td>4.93</td>
<td>1.73</td>
</tr>
<tr>
<td>64640</td>
<td>Other peripheral nerve or branch</td>
<td>3.79</td>
<td>2.67</td>
</tr>
</tbody>
</table>


Additional information communicated by AMA’s CPT Education and Information Services to Myoscience on 4/8/13 includes:
- Using fluoroscopic guidance is separately reported.
- Because each individually separate peripheral nerve root neurolytic block is reported as destruction of a peripheral nerve, it may be appropriate to report CPT 64640 multiple times. In those instances, it is suggested that Modifier 59 (Distinct Procedural Services) be appended as well.

A copy of the AMA’s correspondence is 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**

<table>
<thead>
<tr>
<th>CPT</th>
<th>Description</th>
<th>Physician Fee (Non-Facility) Total RVU=3.79</th>
<th>Physician Fee (Facility) Total RVU=2.67</th>
<th>Hospital APC #5443 Level III Nerve Injections</th>
<th>HOPPS</th>
<th>ASC</th>
</tr>
</thead>
<tbody>
<tr>
<td>64640</td>
<td>Other peripheral nerve or branch</td>
<td>$135.70</td>
<td>$95.60</td>
<td>$822.10</td>
<td>$88.48</td>
<td></td>
</tr>
</tbody>
</table>

Depending upon a facility’s payer contracts, Materials Managers may also want to report the iovera° probe with a Level II HCPCS supply code, such as but not limited to A4210 (needle-free injection device), A4649 (Surgical supply; miscellaneous) or C2618 (Probe/needle cryoablation).

**References:**