This information is provided for general reference and informational purposes only. Each health care provider is ultimately responsible for determining the appropriate codes, coverage, and payment for individual patients. Pacira does not guarantee third-party coverage or payment for the iovera° treatment or reimburse for claims that are denied by third-party payers.

Please see Important Safety Information on back cover. For more information, visit www.iovera.com.
System description

The iovera° system is intended to treat peripheral nerves through the application of intense (extreme) cold via closed-end needles called “Smart Tips.” This treatment temporarily prevents the peripheral nerves from transmitting pain signals to the brain. This technique is described as cryoanalgesia or cryoneurolysis.

Since the temperature (-88° C) and duration (approximately 60-106 seconds) of individual treatment cycles are controlled by the iovera° system, the structural elements of the nerve bundle remain intact, allowing for complete regeneration and functional recovery of the nerve.¹

Clinical value

Cryoanalgesia has been used clinically for decades to provide temporary pain relief.² A large body of clinical work and commercial use over the past 50 years demonstrates relief for patients with various types of pain. Because peripheral sensory nerve function is temporarily disrupted due to the destruction of the axon and myelin sheath, pain relief is provided until nerve regeneration occurs.

Please see Important Safety Information on back cover.
The iovera° procedure (for treating superficial and deep genicular nerves)

The iovera° system has a family of Smart Tips to treat anterior (superficial) and posterior (deep) genicular nerves. Smart Tip 309 provides safe and effective treatment of superficial nerves. Studies have shown that treating the anterior femoral cutaneous nerve and the infrapatellar branch of the saphenous nerve can provide relief for anterior knee pain.³,⁴ It may also be necessary to treat the lateral femoral cutaneous nerve. Smart Tips 190 and 155 offer solutions for treating deep genicular nerves. Two branches of the tibial nerve and the common peroneal nerve associated with the sciatic nerve should be treated to alleviate posterior knee pain.⁵-⁷

Indication

The iovera° system 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° system is not indicated for treatment of central nervous system tissue. The iovera° 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.
It is the sole responsibility of the health care provider to correctly report all procedures and therapies. The following information is shared solely for informational and educational purposes.

**PROFESSIONAL COMPONENT**

Contingent upon the patient’s chief complaint and physical examination, CPT code 64640 has been confirmed by the AMA for treatment of peripheral nerves. This code has also been confirmed to be appropriate for the management of peripheral nerve pain caused by osteoarthritis by the AAOS Coding Coverage and Reimbursement Committee.

<table>
<thead>
<tr>
<th>CPT Code</th>
<th>Definition</th>
<th>Total Non-Facility RVUs</th>
<th>Total Facility RVUs</th>
<th>Physician Fee Schedule (Non-Facility)</th>
<th>Physician Fee Schedule (Facility)</th>
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</thead>
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<tr>
<td>64640</td>
<td>Destruction by neurolytic agent; other peripheral nerve or branch</td>
<td>7.05</td>
<td>3.38</td>
<td>$254.43</td>
<td>$121.98</td>
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<td>64624</td>
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<td>11.57</td>
<td>4.23</td>
<td>$417.56</td>
<td>$152.66</td>
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As of 1/24/2020.
Source: Centers for Medicare and Medicaid Services (CMS), as of 2/24/2020. CMS 2020 (national average) final fee schedules, based on a 2020 Conversion Factor of 36.09. Subject to change based on CMS updates.

Important

Approaches for nerve identification may vary and include nerve stimulators and guided imaging; reimbursement associated with such approaches will differ by payer.
## FACILITY COMPONENT

### Facility Reimbursement

<table>
<thead>
<tr>
<th>CPT Code</th>
<th>Definition</th>
<th>APC</th>
<th>HOPD Fee</th>
<th>ASC Fee</th>
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<tbody>
<tr>
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<td></td>
<td>Procedure</td>
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</tr>
</tbody>
</table>

As of 1/24/2020.
Source: CMS, as of 2/24/2020. CMS 2020 (national average) final fee schedules, based on a 2020 Conversion Factor of 36.09. Subject to change based on CMS updates.

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AAOS=American Academy of Orthopaedic Surgeons; AMA=American Medical Association; APC=Ambulatory Payment Classification; ASC=ambulatory surgery center; CPT=Current Procedural Terminology; HOPD=Hospital Outpatient Department; ICD-10-CM=International Classification of Diseases, Tenth Revision, Clinical Modification; RVU=relative value unit.
Contraindications

The iovera° system is contraindicated for use in patients with the following:
- Cryoglobulinemia, paroxysmal cold hemoglobinuria, cold urticaria, Raynaud’s disease, and open and/or infected wounds at or near the treatment site

Potential complications

As with any surgical treatment that uses needle-based therapy and local anesthesia, there is a potential for site-specific reactions, including, but not limited to:
- Ecchymosis, edema, erythema, local pain and/or tenderness, and localized dysesthesia

Proper use of the device as described in the User Guide can help reduce or prevent the following complications:
- At the treatment site(s): injury to the skin related to application of cold or heat, hyper- or hypopigmentation, and skin dimpling
- Outside the treatment site(s): loss of motor function

Inquiries related to coding and reimbursement can be directed to the Reimbursement Helpline at 1-855-793-9727 or emailed to reimbursement@pacira.com

References:

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