

iovera[®]

CODING AND REIMBURSEMENT

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.

For more information on iovera[®] and for Important Safety Information, visit www.ioverapro.com



iovera[®]

The iovera^o system

Indication

The iovera^o 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^o system is not indicated for treatment of central nervous system tissue.

When stimulation compatible components are used, the iovera^o system can also facilitate target nerve location by conducting electrical nerve stimulation from a compatible 3rd party nerve stimulator.

System description

The iovera^o 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 cryoneurolysis.

Since the temperature (-88 °C) and duration (approximately 60-90 seconds) of individual treatment cycles are controlled by the iovera^o system, the structural elements of the nerve bundle remain intact, allowing for complete regeneration and functional recovery of the nerve.

The iovera^o treatment can be done with anatomical landmark technique, ultrasound, or nerve stimulation.



[Click here](#) or scan QR code to access the AMA CPT Assistant



AMA=American Medical Association; CPT=current procedural terminology.

The iovera[®] procedure for knee pain¹

Several patient types can benefit from the iovera[®] procedure:

- Patients chronically cycling through NSAIDs, injections, and opioids to manage their OA knee pain
- Patients who hesitate or wish to delay surgery (eg, until after an event or season) (presurgery)
- Patients who are planning for TKA surgery and want to recover and rehab with targeted pain relief (prehabilitation)
- Patients looking to minimize pain while healing or manage ongoing postsurgical knee pain (postsurgery)

In patients with OA knee pain, there was a 56% reduction in WOMAC pain scores at 90 days ($P=0.0061$), a significant improvement in physical function ($P=0.017$), and a reduction in stiffness ($P=0.03$).² In patients with TKA, there was a 2X reduction in pain scores, a 45% reduction in opioid use,³ and improved recovery of the range of motion.⁴



Ice ball for illustrative purposes.

NSAID=non-steroidal anti-inflammatory drug; OA=osteoarthritis; TKA=total knee arthroplasty;
WOMAC=Western Ontario and McMaster Universities Osteoarthritis Index.



iovera[®] 3

Coding, coverage, and reimbursement considerations

| CPT Code | 64640 | 64624 |
|------------|---|--|
| Definition | Destruction by neurolytic agent; other peripheral nerve or branch | Destruction by neurolytic agent, genicular nerve branches including imaging guidance, when performed |

iovera[®] can be used with or without ultrasound. The billing code for ultrasound is **76942**. This does not apply to 64624, which includes imaging guidance.

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.

Reimbursement

- The diagnosis associated with the use of cryoneurolysis with iovera[®] may include knee pain (ICD-10-CM code M25.56X) or osteoarthritis of the knee (M17.X)
 - The X is replaced with “1” to identify the right knee and “2” to identify the left knee
 - CPT code 64640 has a medically unlikely edit (MUE) that equals 5, which allows you to bill up to 5 nerves or nerve branches
- CPT code 64624 has an MUE of 1 and defines all 3 of the specified nerves as 1 billable unit. It requires the destruction of each of the following genicular nerve branches: superolateral, superomedial, and inferomedial
 - If a neurolytic agent for the purposes of destruction is not applied to all of these nerve branches, report 64624 with modifier 52

Considerations for cryoneurolysis of multiple nerves

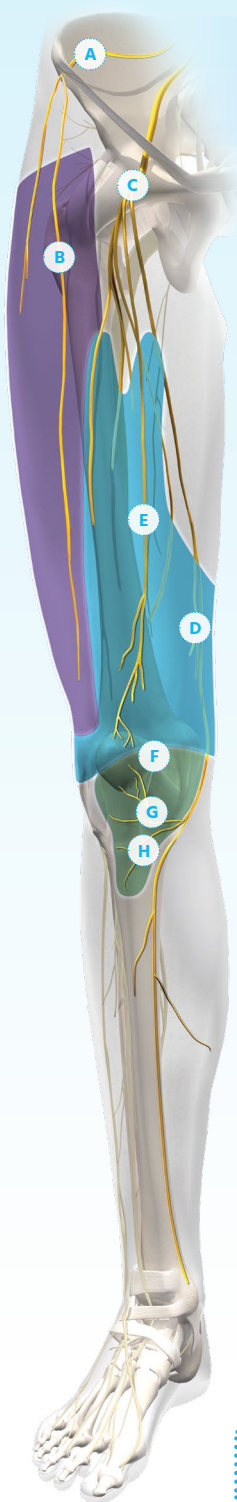
For reimbursement purposes, the treatment of multiple nerves is considered as multiple procedures. Although the treatment protocol is often performed during a single visit, each superficial nerve treated using 64640 is considered an individual procedure.

When more than 1 procedure is performed, the multiple procedure rule applies and results in different reimbursement rates for each procedure. Reimbursement for treated nerves is as follows:

| Nerve treated | First | Second through fifth |
|--------------------|-------|----------------------|
| Reimbursement rate | 100% | 50% each |

▶ The proper reimbursement approach and amount will vary by payer

ICD-10-CM=International Classification of Diseases, Tenth Revision, Clinical Modification.



When iovera® is utilized for peripheral nerve knee pain, CPT code 64640 can be used to indicate treatment of the following associated nerves or nerve branches:

- A Lateral femoral cutaneous nerve**
- B Intermediate lateral femoral cutaneous nerve**
- C Anterior femoral cutaneous nerve**
- D Medial femoral cutaneous nerve**
- E Intermediate medial femoral cutaneous nerve**
- F Suprapatellar branch of the saphenous nerve**
- G Superior branch of the infrapatellar branch of the saphenous nerve**
- H Inferior branch of the infrapatellar branch of the saphenous nerve**

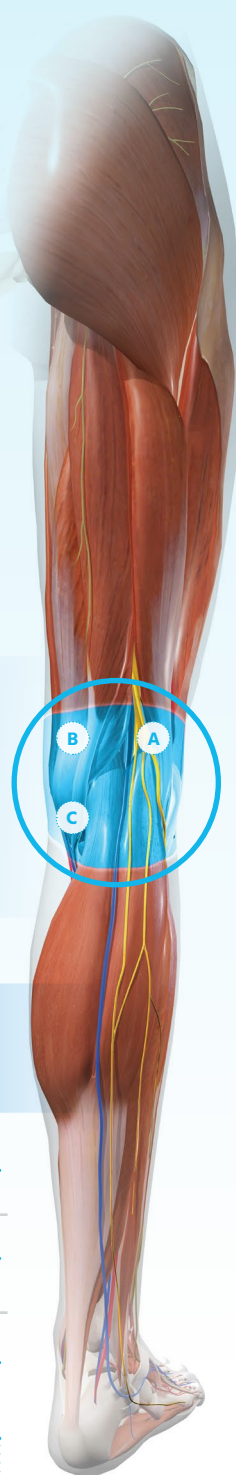
CPT code 64640 can be billed for up to 5 nerves or nerve branches.

These nerves are treated together, and in the event that all 3 nerves are not treated, a modifier should be used.

When iovera® is utilized for posterior (deep genicular) knee pain, CPT code 64624 can be used to indicate treatment of the following associated nerves:

- Superolateral**
(superolateral articulating branch of the common peroneal nerve) **A**
- Superomedial**
(superomedial articulating branch of the tibial nerve) **B**
- Inferomedial**
(inferomedial articulating branch of the tibial nerve) **C**

These procedures can be performed with an ultrasound using **CPT code 76942**. This does not apply to 64624, which includes imaging guidance.



iovera®

Coding, coverage, and reimbursement considerations (cont'd)

Professional component*

| | Total Non-Facility RVU | Non-Facility Payment | Total Facility RVU | Facility Payment | Non-Facility and Facility wRVU | Global Period |
|--------------|------------------------|----------------------|--------------------|------------------|--------------------------------|---------------|
| 64640 | 7.37 | \$249.75 | 3.5 | \$118.61 | 1.98 | 10 days |
| 64624 | 11.64 | \$394.45 | 4.31 | \$146.05 | 2.5 | 10 days |

Facility refers to HOPDs or ASCs, while non-facility refers to an office or a clinic that is not provider-based (eg, hospital).



When iovera[®] is utilized for anterior (superficial genicular) knee pain and TKA incision-related pain, CPT code 64640 can be used to indicate treatment of up to 5 nerves or nerve branches.

Facility component

Facility reimbursement*

| CPT Code | APC | HOPD Payment | ASC Payment |
|----------|------------------------------------|--------------|-------------|
| 64640 | #5443 Level II Nerve Injections | \$852.18 | \$176.21 |
| 64624 | #5431 Level I Nerve Procedure | \$1797.52 | \$853.93 |



If the deep genicular nerves are treated (CPT 64624) and a superficial nerve is treated (CPT 64640), the superficial nerve treatment would not be separately reimbursed by Medicare for HOPDs.

APC=ambulatory payment classification; ASC=ambulatory surgery center; CMS=Centers for Medicare and Medicaid Services; HOPD=hospital outpatient department; RVU=relative value unit; wRVU=work relative value unit.
*Source: CMS, as of 3/1/2023. CMS 2023 (national average) final fee schedules, based on a 2023 Conversion Factor of 33.88720. Subject to change based on CMS updates.

Mid-level provider information

Mid-level providers (eg, nurse practitioners, physician assistants) may be permitted to perform iovera[®] treatments depending on individual state licensing scope of practice. Mid-level providers should confirm the scope of practice with their state licensing board before performing iovera[®] treatments. Reimbursement rates for mid-level providers may differ from physicians.⁵ Improper billing to the appropriate physicians or mid-level providers may lead to no reimbursement.

Documentation checklist

Be sure to document key information in operative notes, such as:

- ✓ Patient Identifying Information
- ✓ Date of service
- ✓ Rendering provider with credentials
- ✓ Pre-procedure diagnosis
- ✓ Post-procedure diagnosis
- ✓ A brief description of the patient's medical history and reason for the procedure
- ✓ Detailed description of the procedure
- ✓ All nerves treated with iovera[®]
- ✓ The use of ultrasound guidance, if applicable
- ✓ The patient's response to treatment



iovera[®] 7

Further guidance and support

Clinician reporting of iovera° for bilateral knees

If iovera° is performed bilaterally on the knees, reporting is based on payer policy. It may be billed in the following ways:

- LT and RT on 2 separate lines per CPT code (applies to facility reimbursement)
- Modifier “50” on 1 line per CPT code
- Two units of a CPT code on 2 separate lines, with modifier “50” appended to the second line

In the past, the AMA has indicated that code 64999 (*unlisted procedure, nervous system*) could be used for cryoneurolysis. Although 64999 may still be used to appropriately report factors related to a cryoneurolytic procedure, **iovera° utilization should not be reported by using 64999**. As with any coding submission, appropriate supporting evidence should be provided to ensure the correct code is being used.

The following codes should **NOT** be used for iovera°

A number of codes, specifically **category III codes 0440T through 0442T**, address a similar but distinct procedure. They refer to cryoablation, and not cryoneurolysis; the codes to the right should not be used to specify the use of iovera°.

| | |
|--------------|--|
| 0440T | Ablation, percutaneous, cryoablation, includes imaging guidance; upper extremity distal/peripheral nerve |
| 0441T | Lower extremity distal/peripheral nerve |
| 0442T | Nerve plexus or other truncal nerve (eg, brachial plexus, pudendal nerve) |

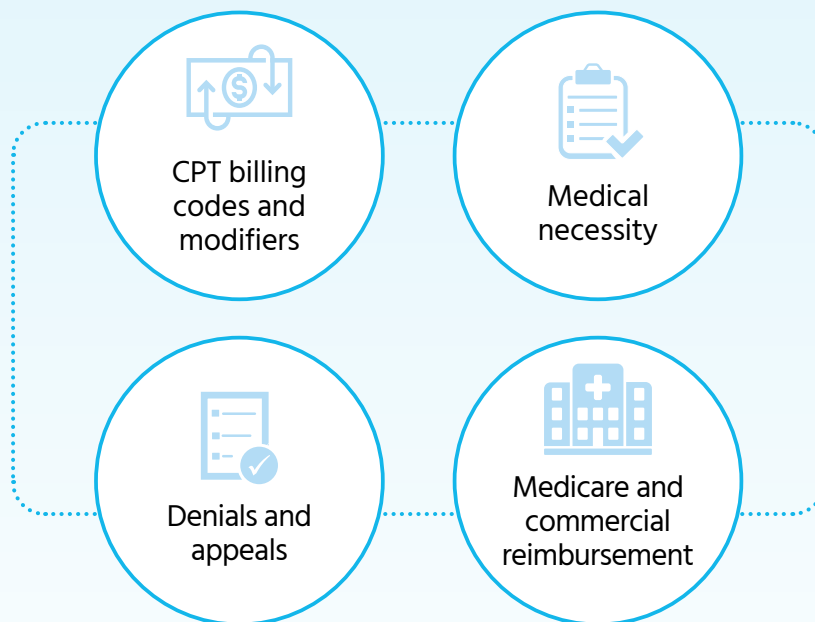


Individuals with current access to the AMA CPT Assistant can always cross-reference the latest available guidance on coding protocols

LT=left; RT=right.

You can contact the Reimbursement Helpline
at **1-855-793-9727** or **reimbursement@pacira.com**

Our dedicated reimbursement experts are available to ensure
you have all required information or documentation about:



Please feel free to contact the Helpline even before iovera[®]
is used so that questions or potential reimbursement issues
can be addressed ahead of time.

The information in this resource 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.



iovera[®] 9

Sample scenarios

| | | Physician | | | | Facility | |
|---|------------------------------------|---------------------------|-------------------------|--|---------------------|----------------|--|
| | | Office (Site 11) | | ASC (Site 24) HOPD (Site 22, on-campus; Site 19, off-campus) | | ASC (Site 24) | HOPD (Site 22, on-campus; Site 19, off-campus) |
| | | | | | | | |
| 3 PERIPHERAL NERVE TREATMENTS* | CPT/HCPCS Code | Total Non Facility RVU | Non-Facility Payment | Total Facility RVU | Facility Payment | ASC Payment | HOPD Payment |
| | 64640 | 7.37 | \$249.75 | 3.50 | \$118.61 | \$176.21 | \$852.18 |
| | 64640 | 3.69 | \$124.88 | 1.75 | \$59.31 | \$88.11 | \$426.09 |
| | 64640 | 3.69 | \$124.88 | 1.75 | \$59.31 | \$88.11 | \$426.09 |
| | TOTAL | 14.74 | \$499.50 | 7.00 | \$237.22 | \$352.42 | \$1704.36 |
| | 76942-Ultrasound Guidance | 1.74 | \$58.96 | 0.90 | \$30.50 | N/A | N/A |
| TOTAL | | 16.48 | \$558.46 | 7.90 | \$267.72 | \$352.42 | \$1704.36 |
| 5 PERIPHERAL NERVE TREATMENTS† | 64640 | 7.37 | \$249.75 | 3.50 | \$118.61 | \$176.21 | \$852.18 |
| | 64640 | 3.69 | \$124.88 | 1.75 | \$59.31 | \$88.11 | \$426.09 |
| | 64640 | 3.69 | \$124.88 | 1.75 | \$59.31 | \$88.11 | \$426.09 |
| | 64640 | 3.69 | \$124.88 | 1.75 | \$59.31 | \$88.11 | \$426.09 |
| | 64640 | 3.69 | \$124.88 | 1.75 | \$59.31 | \$88.11 | \$426.09 |
| | TOTAL | 22.11 | \$749.25 | 10.50 | \$355.83 | \$528.63 | \$2556.54 |
| 76942-Ultrasound Guidance | | 1.74 | \$58.96 | 0.90 | \$30.50 | N/A | N/A |
| TOTAL | | 23.85 | \$808.21 | 11.40 | \$386.33 | \$528.63 | \$2556.54 |
| DEEP GENICULAR TREATMENT ONLY* | 64624 (Includes Image Guidance) | 11.64 | \$394.45 | 4.31 | \$146.05 | \$853.93 | \$1797.52 |
| TOTAL | | 11.64 | \$394.45 | 4.31 | \$146.05 | \$853.93 | \$1797.52 |
| DEEP GENICULAR & SINGLE PERIPHERAL NERVE TREATMENT§ | 64624 (Includes Image Guidance) | 11.64 | \$394.45 | 4.31 | \$146.05 | \$853.93 | \$1797.52 |
| | 64640 | 3.69 | \$124.88 | 1.75 | \$59.31 | \$88.11 | -.1.† |
| TOTAL | | 15.33 | \$519.33 | 6.06 | \$205.36 | \$942.04 | \$1797.52 |
| DEEP GENICULAR & 3 PERIPHERAL NERVE TREATMENTS | 64624 (Includes Image Guidance) | 11.64 | \$394.45 | 4.31 | \$146.05 | \$853.93 | \$1797.52 |
| | 64640 | 3.69 | \$124.88 | 1.75 | \$59.31 | \$88.11 | -.1.† |
| | 64640 | 3.69 | \$124.88 | 1.75 | \$59.31 | \$88.11 | -.1.† |
| | 64640 | 3.69 | \$124.88 | 1.75 | \$59.31 | \$88.11 | -.1.† |
| TOTAL | | 22.71 | \$769.08 | 9.56 | \$323.97 | \$1118.25 | \$1797.52 |

AFCN=anterior femoral cutaneous nerve; HCPCS=Healthcare Common Procedure Coding System; ISN=infrapatellar branch of the saphenous nerve; LFCN=lateral femoral cutaneous nerve; N/A=not applicable.

Calculation Source: CMS, as of 3/1/2023. CMS 2023 (national average) final fee schedules, based on a 2023 Conversion Factor of 33.88720.

*AFCN and 2 branches of the ISN.

†Superficial genicular nerves such as AFCN, ISN, 2 branches of the ISN, and LFCN.

‡Superolateral, superomedial, and inferomedial nerves.

§Superolateral, superomedial, and inferomedial nerves and AFCN.

||Superolateral, superomedial, and inferomedial nerves and AFCN and 2 branches of the ISN.

*Claims with at least 1 J1 procedure code are separated from the standard Outpatient Prospective Payment System (OPPS) modeling and subjected to comprehensive specific modeling.

In contrast to OPPS modeling, costs on the claim from major OPPS procedure codes (status indicators P, S, T, and V), lower ranked comprehensive procedure codes (status indicator J1), non-pass-through drugs and biologics (status indicator K), and blood products (status indicator R) are all packaged into the primary comprehensive procedure.

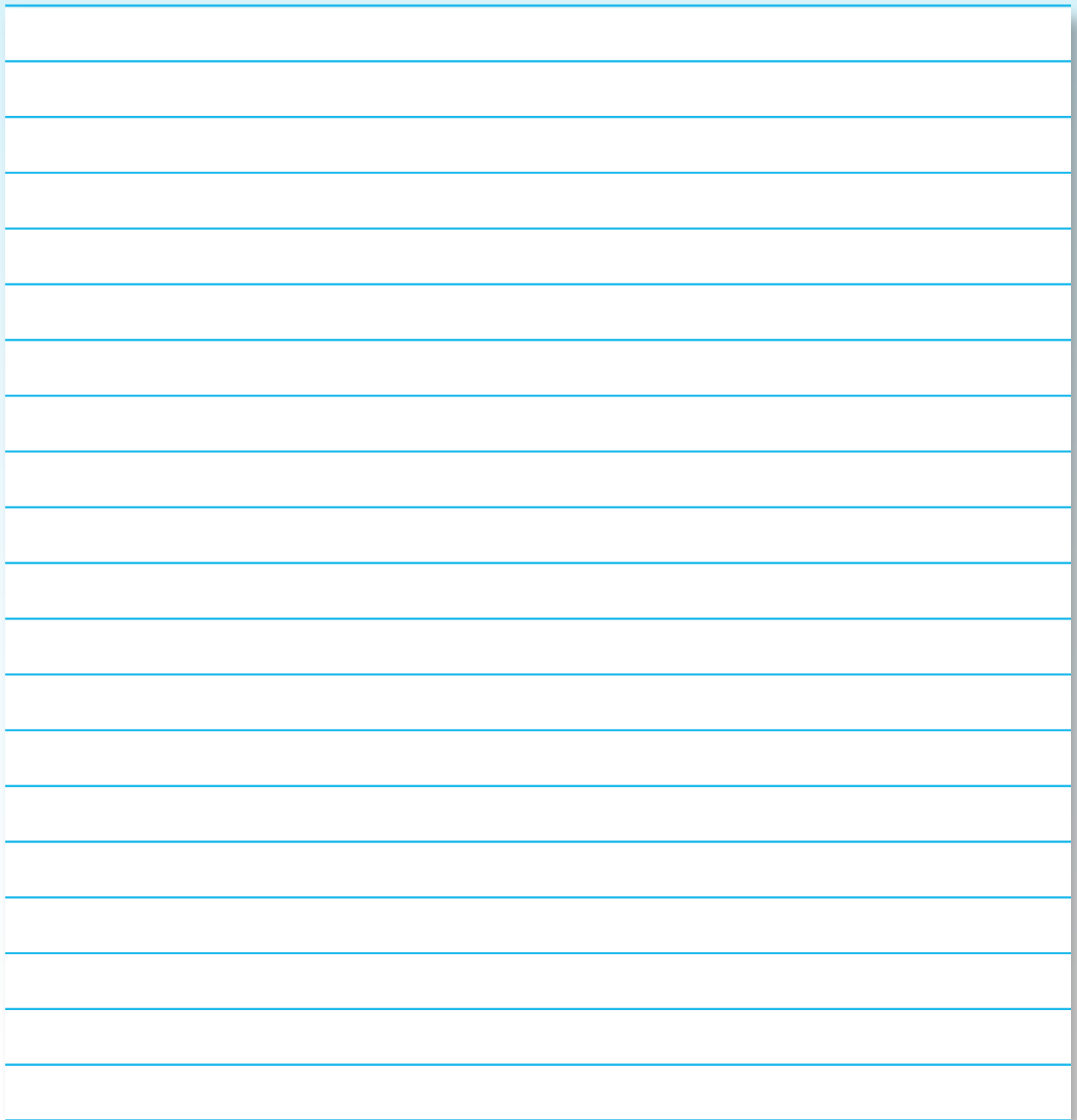
¶In the HOPD, the facility component is NOT reimbursed when BOTH 64624 and 64640 are billed.

NOTE: All subsequent procedures after the first will be reimbursed at 50% of the rate.

Global period for 64640 = 10 days.

Global period for 64624 = 10 days.

Notes





Please see Important Safety Information at www.ioverapro.com

References: 1. Who can benefit from iovera®? Accessed March 27, 2023. <https://www.ioverapro.com/appropriate-patients> 2. Radnovich R, Scott D, Patel AT, et al. Cryoneurolysis to treat the pain and symptoms of knee osteoarthritis: a multicenter, randomized, double-blind, sham-controlled trial. *Osteoarthritis Cartilage*. 2017;25(8):1247-1256. 3. Dasa V, Lensing G, Parsons M, Harris J, Volaufova J, Bliss R. Percutaneous freezing of sensory nerves prior to total knee arthroplasty. *Knee*. 2016;23(3):523-528. 4. Urban JA, Dolesh K, Martin E. A multimodal pain management protocol including preoperative cryoneurolysis for total knee arthroplasty to reduce pain, opioid consumption, and length of stay. *Arthroplast Today*. 2021;10:87-92. 5. American Academy of Physician Associates. CMS releases 2022 physician fee schedule rule. Published November 10, 2021. Accessed August 11, 2022. <https://www.aapa.org/news-central/2021/11/cms-releases-2022-physician-fee-schedule-rule/>

©2023 Pacira BioSciences, Inc. All rights reserved. iovera® is a trademark of Pacira CryoTech, Inc., a wholly owned subsidiary of Pacira BioSciences, Inc.
PP-IO-US-0861 04/23



iovera®

PACIRA
BIOSCIENCES, INC.