**Template Letter of Medical Necessity for iovera° Treatment**

[Date]

[Payer Name]

[Payer Address]

Attn: [Name, Department]

Subject: Determination of medical necessity for:

[Patient Name]

[Policy Number/Group #/Patient ID #]

To Whom It May Concern:

I am requesting [Select: Prior Authorization and/or a Determination Of Medical Necessity] on behalf of my patient, [Patient’s Name], for peripheral nerve treatment using thermal energy (cryoneurolysis) in accordance with the FDA-cleared indication of the iovera° system.

[Mr./Mrs./Ms.] [Patient’s Name] is a(n) [Age]-year old [Gender] who suffers from [Diagnosis]. *(Detail the patient’s historical medical condition, previous treatments, and relevant clinical information supporting the utilization of iovera° system.)* Patient chart documentation has been included for your review.

[Include this paragraph for treating knee pain]

To effectively treat anterior knee pain in this patient, it is recommended that the following nerves be treated with cryoneurolysis. The nerves include the anterior femoral cutaneous nerve (AFCN) and the infrapatellar saphenous nerve (ISN).1((AND/OR))

To effectively treat posterior knee pain in this patient, it is recommended that the following nerves be treated with cryoneurolysis2:

* + - Superolateral (superolateral articulating branch of the Common Peroneal nerve)
		- Superomedial (superomedial articulating branch of the Tibial nerve)
		- Inferomedial (inferomedial articulating branch of the Tibial nerve)

**Procedure Description:**

Cryoneurolysis has been well characterized in pain relief and substantial published literature exists regarding this modality. The treatment temporarily blocks nerve conduction along peripheral nerve pathways using the application of intense, highly focused cold (thermal energy) via a closed tip needle by cryogenic fluid (liquid nitrous oxide [N20]) inserted through the skin to the selected site for the treatment of pain. A frozen zone forms around the tip of the needle assembly and the adjacent nerve.

This procedure is designed to temporarily degenerate the nerve fiber that sends pain signals.

Various nerve location techniques may be utilized, including: anatomic landmarks, nerve stimulation, non-invasive ultrasound, and/or fluoroscopy. Once the location of the nerve has been determined, a small amount of local anesthetic is administered to the area. The device is then positioned at the treatment site, the closed tip needle is inserted, and the focused cold (thermal energy) is applied near/adjacent to the target nerve, stopping pain signals.

Sedation is not required during the procedure as to allow the patient to give real-time feedback to the physician. This provides additional confirmation that the target nerve has been treated.

This therapy is reasonable and necessary for [Patient’s Name] condition. Clinical publications on cryoneurolysis are attached for your reference.

Please contact me at [Phone Number / Email Address] for further information or questions.

Sincerely,

[Physician Name]

**References**

1. “Percutaneous freezing of sensory nerves prior to total knee arthroplasty,” V. Dasa, G. Lensing, M. Parsons, J Harris, J Volaufova, R. Bliss, The Knee (23), 2016 523-528.
2. “Kennedy JC, Alexander IJ, Hayes KC. Nerve supply of the human knee and its functional importance. *Am J Sports Med*. 1982;10(6):329-335.

**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.

**IMPORTANT SAFETY INFORMATION**

**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