

<b>Case Number:</b>	CM15-0108167		
<b>Date Assigned:</b>	06/12/2015	<b>Date of Injury:</b>	10/01/2010
<b>Decision Date:</b>	07/30/2015	<b>UR Denial Date:</b>	05/14/2015
<b>Priority:</b>	Standard	<b>Application Received:</b>	06/04/2015

### HOW THE IMR FINAL DETERMINATION WAS MADE

MAXIMUS Federal Services sent the complete case file to an expert reviewer. He/she has no affiliation with the employer, employee, providers or the claims administrator. He/she has been in active clinical practice for more than five years and is currently working at least 24 hours a week in active practice. The expert reviewer was selected based on his/her clinical experience, education, background, and expertise in the same or similar specialties that evaluate and/or treat the medical condition and disputed items/Service. He/she is familiar with governing laws and regulations, including the strength of evidence hierarchy that applies to Independent Medical Review determinations.

The Expert Reviewer has the following credentials:

State(s) of Licensure: California

Certification(s)/Specialty: Physical Medicine & Rehabilitation

### CLINICAL CASE SUMMARY

The expert reviewer developed the following clinical case summary based on a review of the case file, including all medical records:

The injured worker is a 55-year-old female with an industrial injury dated 10/01/2010. Her diagnoses included pain in joint lower leg, bilateral knees with degenerative joint disease, meniscus injury and ACL tears and plantar fibromatosis - bilateral. Comorbid diagnosis was hypertension. Prior treatments include muscle relaxants, compression sleeve for the left knee, TENS unit and weight bearing knee brace. She presents on 04/10/2015 with complaints of right knee pain with radiation of pain into her lateral thigh and down into her medial calf. She also notes significant left knee pain secondary to compensatory use. Pain is made significantly better with the use of medication as well as rest. The injured worker notes 40% pain relief with her medications. Physical exam noted left knee was positive for tenderness to palpation. The provider documents the most recent x-ray (right knee) showed bone on bone of the lateral compartment had progressed since previous x-rays. There was a mild effusion with tenderness along the lateral joint. Diagnostic reports are documented in progress reports. Formal reports are not in the submitted records. Treatment plan included a lateral unloader knee brace for right knee and cryotherapy of the infrapatellar branch of the saphenous on the right knee. The provider documents the request for cryotherapy is to deaden the nerve and minimize pain. The request is for Iovera sub dermal cooling for the right knee.

### IMR ISSUES, DECISIONS AND RATIONALES

The Final Determination was based on decisions for the disputed items/services set forth below:

## **Iovera Subdermal Cooling for the right knee: Upheld**

**Claims Administrator guideline:** The Claims Administrator did not cite any medical evidence for its decision.

**MAXIMUS guideline:** Decision based on MTUS ACOEM Chapter 12 Low Back Complaints Page(s): 300. Decision based on Non-MTUS Citation Official disability guidelines Knee chapter, Continuous-flow Cryotherapy Knee and Leg (Acute & Chronic) Chapter, Cryotherapy.

**Decision rationale:** Based on the 05/08/15 progress report provided by treating physician, the patient presents with chronic bilateral knee pain. The patient is status post-RIGHT knee surgery, January 2005. The request is for IOVERA SUBDERMAL COOLING FOR THE RIGHT KNEE. Patient's diagnosis per Request for Authorization form dated 05/07/15 includes right knee degenerative joint disease. Diagnosis on 05/08/15 included pain in joint lower leg, bilateral knees with DJD, meniscus injury and ACL tears; and bilateral plantar fibromatosis. Physical examination to RIGHT knee on 02/13/15 was positive for effusion, joint line tenderness. The patient has an antalgic gait and wears a RIGHT knee brace. Treatment to date included surgery, bracing, Suppartz injections, and medications. Patient's medications include Protonix, Zanaflex, Anaprox, Hydrocodone, Hydrochlorothiazide, and Lidoderm patch. The patient is permanent and stationary, per 05/08/15 report. Treatment reports were provided from 01/20/15 - 05/08/15. ACOEM, MTUS and ODG do not address Iovera cryoneuro modulation. The product's website states the following: [www.ioverahealth.com/how\\_it\\_works.php#how\\_it\\_works](http://www.ioverahealth.com/how_it_works.php#how_it_works) "The iovera treatment uses the body's natural response to cold to immediately reduce pain without leaving anything behind. It precisely targets the source of your pain for immediate and lasting relief without the use of drugs or pharmaceuticals. The iovera treatment is FDA cleared to block pain. The iovera treatment is a new way of using a safe and trusted technology, cryotherapy, that goes back to the 1950s. This technology harnesses the power of cold to safely deliver precise treatments to relieve pain. The iovera system has revolutionized the delivery of cryotherapy because the Focused Cold Therapy delivery device enables doctors to deliver controlled doses of cold temperature to immediately stop pain. The device uses liquid nitrous oxide that is contained within the device, and delivers it at very high speeds down a closed-end needle, where it undergoes a phase change. This process draws in heat energy from the surrounding tissue, creating a precise zone of cold to treat the intended nerve. The gaseous nitrous oxide is expelled out from the device, leaving nothing behind in the body. The effect on the nerve, called Wallerian Degeneration, is temporary and allows the nerve to regenerate." ACOEM Guidelines 300 states, "At-home local applications of heat or cold are as effective as those performed by therapists." ODG Guidelines, Knee chapter under Continuous-flow Cryotherapy states: "Recommended as an option after surgery but not for non-surgical treatment. Postoperative use generally may be up to 7 days including home use. In the postoperative setting, continuous-flow cryotherapy units have been proven to decrease pain, inflammation, swelling, and narcotic use." ODG-TWC, Knee and Leg (Acute & Chronic) Chapter under Cryotherapy states: "The AHRQ Comparative Effectiveness Review of PT for knee arthritis concluded that cryotherapy did not improve disability, quality of life, and composite function measures." (Shamliyan, 2012) Per RFA dated 05/07/15, treater requests, "Iovera subdermal cooling of nerves around the knees for pain control otherwise known as cryoneuro modulation." Per 04/09/15 appeal letter, treater states "...my request is cryotherapy of the infrapatellar branch of the saphenous nerve in the right knee

to deaden the nerve to minimize pain." Although "FDA approved," the request for Iovera cryotherapy does not have current guideline support. None of the guidelines currently discusses this device. The treatment is yet experimental and has not gained mainstream approval. The treater does not provide evidence- based support either. ODG does not support cryotherapy for knee pains yet. The request IS NOT medically necessary.