Clinical Policy Title: Infrared (IR) therapy

Clinical Policy Number: 18.02.03

Effective Date: October 1, 2014
Initial Review Date: May 21, 2014
Most Recent Review Date: May 18, 2016
Next Review Date: May 2017

Policy contains:
- Near-infrared light therapy.
- Far-infrared light therapy.

Related Policies:
None.

ABOUT THIS POLICY: Arbor Health Plan has developed clinical policies to assist with making coverage determinations. Arbor Health Plan’s clinical policies are based on guidelines from established industry sources, such as the Centers for Medicare & Medicaid Services (CMS), state regulatory agencies, the American Medical Association (AMA), medical specialty professional societies, and peer-reviewed professional literature. These clinical policies along with other sources, such as plan benefits and state and federal laws and regulatory requirements, including any state- or plan-specific definition of “medically necessary,” and the specific facts of the particular situation are considered by Arbor Health Plan when making coverage determinations. In the event of conflict between this clinical policy and plan benefits and/or state or federal laws and/or regulatory requirements, the plan benefits and/or state and federal laws and/or regulatory requirements shall control. Arbor Health Plan’s clinical policies are for informational purposes only and not intended as medical advice or to direct treatment. Physicians and other health care providers are solely responsible for the treatment decisions for their patients. Arbor Health Plan’s clinical policies are reflective of evidence-based medicine at the time of review. As medical science evolves, Arbor Health Plan will update its clinical policies as necessary. Arbor Health Plan’s clinical policies are not guarantees of payment.

Coverage policy

Arbor Health Plan considers the use of infrared (IR) therapy to be clinically proven and, therefore, medically necessary when one of the following criteria is met:

- For treatment of early stage (Stage I or II) internal hemorrhoids that are painful or persistently bleeding after conservative treatment (e.g., oral laxatives, local ointments, non-constipating diets).

OR

- As adjunctive treatment when used as a heat modality in physical therapy.

Limitations:

All other uses of IR therapy are not medically necessary.
Alternative covered services:

- Rubber band ligation.
- Sclerotherapy.
- Bipolar diathermy or cautery.
- Surgical hemorrhoidectomy.

Background

IR light is electromagnetic radiation with longer wavelengths than those of visible light, extending from the nominal red edge of the visible spectrum at 0.7 micrometers (µm) to 1000 µm. This region is further divided into near-IR, middle-IR and far-IR (Liew 2001).

IR therapy (IT) is a type of light therapy that uses low energy light within the IR spectrum. Although the exact mechanism is unclear, IT is believed to promote photochemical, photophysical and photobiological effects in cells and tissues, without causing temperature to rise above 98 °F (Anodyne 2014).

Several devices are available to deliver IT, but differ in their methods (wavelength, pulse rate, intensity, etc.), design (total surface area) and application (handheld or attachable). Medical applications for IT incorporate either near-IR light using laser or light emitting diodes (LEDs) or far-IR light applied in a sauna. Near-IR LED devices are used to treat an area of the skin and adjacent subcutaneous tissues of a patient, whereby an array of juxtaposed IR LEDs is fixed to a flexible pad to maintain skin contact.

Near-IR laser (also referred to as low-energy, low-level or cold laser) has low power with wavelengths of 600-1000 nanometers (nm) or greater in certain cases (Chung 2012). When applied to the skin, it does not burn and produces little or no sensation. Near-IR laser is proposed for three main purposes: to promote wound healing, tissue repair, and the prevention of tissue death; to relieve inflammation and edema because of injuries or chronic diseases; and as an analgesic and a treatment for other neurological problems. In addition, near-IR laser is proposed as a treatment for serious neurological conditions such as traumatic brain injury (TBI), stroke, spinal cord injury, and degenerative central nervous system disease (Chung 2012).

IT using far-IR is a form of heat therapy delivered via heated saunas that exposes body tissues to slightly higher temperatures. Far-IR reportedly heats the body and achieves similar effects as a conventional sauna but at more tolerable lower temperatures. The rationale for using far-IR is that the heating gently increases blood flow by expanding capillary blood flow, increasing oxygenation and regeneration of the blood and detoxifying the blood to improve overall health. Its purported medical benefits include treatment of health problems such as high blood pressure, congestive heart failure and rheumatoid arthritis (Mayo Clinic 2014).

Regulatory status

The U.S. Food and Drug Administration (FDA) reclassified in the Title 21 Code of Federal Regulations (21CFR) several earlier IR devices as heating pads, and their approved indications reflect these roots. Now classified as IR lamps, these interventions are Class II Physical Medicine Therapeutic Devices (PMTD, product codes IOB, ILY, NHN, ONH) that emit energy at IR frequencies of approximately 700 nanometers (nm) to 50,000 nm. (21CFR890.5500 2014). Product labeling varies, but generally these devices are intended for adjunctive use to provide relief of minor pain, stiffness and muscle spasm and a temporary increase in local blood circulation.
In addition, the FDA has approved IR lamps for stimulating hair growth (product code OAP), as adjunctive treatment of post-mastectomy lymphedema (product code NZY), electrosurgical cutting and coagulation device and accessories for tissue coagulation (product code GEI) and laser treatment in general and plastic surgery and dermatology (21CFR890.5500 2014, 21CFR807.92 2014, 21CFR875.4400 2014, product code GEX). No devices using far-IR have been approved for medical use, and at least one warning letter was issued to a manufacturer of a far-IR sauna for marketing its product in the U.S. without marketing clearance or approval.

**Staging of internal hemorrhoids**

Internal hemorrhoids are categorized by the Society for Surgery of the Alimentary Tract (SSAT) as follows:

- **Stage I**: Bleeding only, no prolapse
- **Stage II**: Prolapse that reduces spontaneously, with or without bleeding
- **Stage III**: Prolapse that requires manual reduction, with or without bleeding
- **Stage IV**: Irreducible prolapsed hemorrhoidal tissue

**Searches**

Arbor Health Plan searched PubMed and the databases of:

- UK National Health Services Center for Reviews and Dissemination.
- Agency for Healthcare Research and Quality’s National Guideline Clearinghouse and other evidence-based practice centers.
- The Centers for Medicare & Medicaid Services (CMS).

We conducted searches on April 26, 2016. Searched terms were: "IR therapy (MeSH)" and "light therapy (MeSH)."

We included:

- **Systematic reviews**, which pool results from multiple studies to achieve larger sample sizes and greater precision of effect estimation than in smaller primary studies. Systematic reviews use predetermined transparent methods to minimize bias, effectively treating the review as a scientific endeavor, and are thus rated highest in evidence-grading hierarchies.
- **Guidelines based on systematic reviews**.
- **Economic analyses**, such as cost-effectiveness, and benefit or utility studies (but not simple cost studies), reporting both costs and outcomes — sometimes referred to as efficiency studies — which also rank near the top of evidence hierarchies.

**Findings**

Fifteen systematic and narrative reviews were identified for this policy. Fourteen reviews examined the effectiveness of near-IR light therapy for treating: internal hemorrhoids (Johanson 1992, MacRae 2002); anal canal intraepithelial neoplasia (Macaya 2012); traumatic brain injury (TBI) (Mories 2015); Alzheimer and Parkinson disease (Johnstone 2015); arteriovenous (AV) shunt patency (Choi 2016); diabetic peripheral neuropathy (Ites 2011, Hayes 2008); acne vulgaris (Hamilton 2009, Hayes 2009); musculoskeletal pain (Chow 2005, Hayes 2009); restless leg syndrome (Wilt 2012); and for preventing oral mucositis (Migliorati 2013). One systematic review examined the effectiveness of far-IR sauna therapy for reducing cardiovascular risk factors (Beever 2009). No economic analyses were identified for this policy.
• **Internal hemorrhoids:** There is sufficient medical evidence to support the use of IR therapy (also called IR coagulation) as a treatment option for persons with early stage (Stage I or II) internal hemorrhoids who have failed conservative treatment (e.g., oral laxatives, local ointments, nonconstipating diets). The Standards Practice Task Force of the American Society of Colon and Rectal Surgeons recommends rubber band ligation (RBL), sclerotherapy and IR coagulation as effective treatment options for most patients with Stage I, II, and III hemorrhoid disease based on moderate quality evidence (Rivadeneira 2011). The American Gastroenterological Association states that second-degree, relatively small and third degree hemorrhoids can be treated with nonoperative therapy, including IR photocoagulation (Madoff 2004).

Although the incidence of complications is low, perianal sepsis is a potential life-threatening complication with all of the office-based procedures. Each procedure has a variable recurrence rate and each may require repeated applications (Rivadeneira 2011, Madoff 2004). Previous reports on IR coagulation found high rates of recurrence with more advanced grades III and IV hemorrhoids. RBL, although more effective in controlling symptoms and obliterating grades I-III hemorrhoids than IR coagulation or sclerotherapy, is associated with more pain and discomfort to the patient. RBL can treat up to three hemorrhoids in a single session, while IR coagulation can treat up to six hemorrhoids per session. Because of the risk of postoperative hemorrhage, RBL should not be performed in patients receiving anticoagulants (e.g., warfarin). Sclerotherapy and IT may be considered in patients who are on anticoagulant therapy. Choice of treatment depends on several factors such as patient symptoms, the number of hemorrhoids, the hemorrhoidal grade, bleeding tendency, surgical experience and patient preferences (Rivadeneira 2011, Madoff 2004).

• **Thermotherapy:** There is sufficient moderate-quality medical evidence to support the use of IT for acute or chronic neck musculoskeletal pain. However, larger studies with long-term follow-up are needed to confirm these findings and determine the most effective therapeutic parameters, sites and modes of application. One report found limited evidence of benefit for the use of low-level laser therapy (LLLT) for rheumatoid arthritis using red or near-IR light (Hayes 2009). The Ottawa Panel Evidence-Based Clinical Practice Guidelines Panel found moderate to good quality medical evidence from randomized controlled trials (RCTs) showing that thermotherapy, including IR, should be included as an intervention for the management of rheumatoid arthritis, but they offered no preference for one type of thermotherapy over another. Their findings and recommendations were consistent with other existing guidelines (Ottawa 2004).

• **For all other clinical indications,** there is insufficient medical evidence to support the use of IT.

**Summary of clinical evidence:**

<table>
<thead>
<tr>
<th>Citation</th>
<th>Content, Methods, Recommendations</th>
</tr>
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<tbody>
<tr>
<td>Hemorrhoids</td>
<td>Key points:</td>
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<tr>
<td>A meta-analysis of hemorrhoidal treatments</td>
<td>RBL is more effective than sclerotherapy or IR coagulation, without an increase in complications.</td>
</tr>
<tr>
<td></td>
<td>Hemorrhoidectomy associated with greater effectiveness but more complications.</td>
</tr>
<tr>
<td>Citation</td>
<td>Content, Methods, Recommendations</td>
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| Johanson (1992)| - Systematic review of five trials (n = 863) comparing the efficacy of IR coagulation, injection sclerotherapy and rubber band ligation to determine the optimal nonoperative hemorrhoid treatment.  
- Similar numbers of patients were asymptomatic 12 months after treatment, regardless of initial therapy.  
- RBL associated with fewer recurrences but significantly higher incidence of posttreatment pain.  
- IR coagulation was associated with both fewer and less severe complications. |
| Choi (2016)    | - Authors postulated that near-IR therapy may improve endothelial function and increase AV shunt blood flow and patency in hemodialysis (HD) patients.  
- RCT enrolled 25 HD outpatients and 25 HD controls who were matched for age, sex, and diabetes.  
- Far-IR therapy was administered for 40 minutes 3 times/wk and continued for 12 months.  
- Shunt blood flow was measured by the ultrasound dilution method, whereas pain was measured by a numeric rating scale at baseline, then once per month.  
- One HD patient was transferred to another facility and 7 HD patients stopped far-IR therapy because of an increased body temperature and discomfort.  
- Far-IR therapy improved the needling pain score from 4 to 2 after 1 year, shunt flow increased by 3 months and maintained this change until 1 year post-treatment  
- Control HD patients showed a decrease in blood flow; however, the 1-year unassisted patency with far-IR therapy was not significantly different from control. |
| Johnstone,(2015)| - Near-IR therapy proposed as a neuroprotective or disease-modifying treatment for Alzheimer and Parkinson patients.  
- Near-IR treatment may act at a cellular level, activating intracellular cascades that ultimately contribute to the survival of the target, and possibly neighboring, cells and/or stimulating neurogenesis.  
- Near-IR treatment may be capable of triggering systemic protective mechanisms that can transduce protective effects to the brain  
- Because of its lack of side-effects and neuroprotective potential near-IR treatment is amenable to use in conjunction with other treatments. |
| Morries (2015) | - A retrospective study (n=10) of high-power near-IR laser phototherapy with a Class IV laser to treat TBI.  
- Patients were given ten treatments over the course of 2 months using a high-power near-IR laser (13.2 W/0.89 cm2 at 810 nm or 9 W/0.89 cm2 at 810 nm and 980 nm)  
- Symptoms of headache, sleep disturbance, cognition, mood dysregulation, |
<table>
<thead>
<tr>
<th>Citation</th>
<th>Content, Methods, Recommendations</th>
</tr>
</thead>
<tbody>
<tr>
<td>Migliora (2013)</td>
<td><strong>Key points:</strong></td>
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<tr>
<td>Prevention of oral mucositis</td>
<td>- Systematic review of one RCT and multiple lower level studies.</td>
</tr>
<tr>
<td></td>
<td>- RCT had no major flaws and multiple lower level studies reported consistent positive results using similar laser parameters.</td>
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<tr>
<td></td>
<td>- LLLT at 650 nm wavelength reduced the severity of oral mucositis and pain scores more than LLLT at 750 nm (p=0.06). LLLT at 650 nm well-tolerated and no adverse events noted but effects of modification of laser parameters (e.g., wavelength, fluence, repetition rate of energy delivery, etc.) are unclear.</td>
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<tr>
<td>Macaya (2012)</td>
<td><strong>Key points:</strong></td>
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<tr>
<td>Cochrane review Anal cancer</td>
<td>- Systematic review of treatments for anal canal intraepithelial neoplasia; one RCT of medical treatment only.</td>
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<tr>
<td></td>
<td>- Overall quality rated as poor.</td>
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<td></td>
<td>- Insufficient evidence.</td>
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<tr>
<td>Wilt (2012)</td>
<td><strong>Key points:</strong></td>
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<tr>
<td>(AHRQ)</td>
<td>- Systematic review of treatments for restless less syndrome, including one RCT of near-IR light therapy.</td>
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<tr>
<td>Restless leg syndrome</td>
<td>- Overall quality was rated as poor.</td>
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<td>- Subjects (n=12) received 30-minute near-IR light treatment sessions for four weeks.</td>
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<td>- Symptom scores were more than sham, -13.4 points versus -4.5 points, respectively, with a mean difference (MD) of -9.00 (95 % CI=-13.21 to -4.79).</td>
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<tr>
<td></td>
<td>- Further confirmation needed.</td>
</tr>
<tr>
<td>Ites (2011)</td>
<td><strong>Key points:</strong></td>
</tr>
<tr>
<td>Diabetic peripheral neuropathy</td>
<td>- Systematic review of six studies, including one RCT of four physical therapy interventions — monochromatic IR energy therapy, vibrating insoles, lower extremity strengthening exercises and use of a cane.</td>
</tr>
<tr>
<td></td>
<td>- Overall quality rated as poor.</td>
</tr>
<tr>
<td></td>
<td>- Insufficient evidence.</td>
</tr>
<tr>
<td>Hamilton (2008)</td>
<td><strong>Key points:</strong></td>
</tr>
<tr>
<td>Acne vulgaris</td>
<td>- Systematic review of 25 RCTs of light therapies.</td>
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<tr>
<td></td>
<td>- Overall quality rated as poor due to small sample sizes.</td>
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<tr>
<td></td>
<td>- There were limited or no beneficial effects of light therapy alone for treating acne. Light therapies with blue light, blue-red light and IR radiation sources were more likely to show short term a benefit than yellow, red or green light sources.</td>
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<tr>
<td>Hayes (2009)</td>
<td><strong>Key points:</strong></td>
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<tr>
<td>Acne vulgaris</td>
<td>- Systematic review of phototherapy, including one RCT of near-IR laser.</td>
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<td></td>
<td>- Overall quality was rated poor with study designs were considered flawed.</td>
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<td>- Blue light, red light (or a combination of the two), pulsed dye laser (PDL) and laser light can reduce the severity of mild to moderate facial acne with no serious complications in the short term.</td>
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<td>- Additional well-designed, longer-term RCTs needed.</td>
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<tr>
<td>Beever 2009</td>
<td><strong>Key points</strong></td>
</tr>
<tr>
<td>Cardiovascular risk factors</td>
<td>- Systematic review of nine RCTs and observational studies of far-IR sauna therapy.</td>
</tr>
<tr>
<td>Citation</td>
<td>Content, Methods, Recommendations</td>
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</table>
| Chow (2005)   | *Overall quality rated as poor due to small sample sizes, short duration of study, and use of non-validated symptom score assessments.*  
| Neck pain     | *No adverse events reported in any of the studies.*  
|               | *Inconclusive evidence of effect on cardiovascular risk factor reduction.*                                                                                                                                                                                                                                                                                                                                                                                     |
|               | **Key points:**  
|               | *Systematic review of five RCTs (n = 273).*  
|               | *Quality assessment rated: fair to good.*  
|               | *Limited evidence from four of five studies suggests statistically significant short term improvement after receiving LLLT (compared with control/sham).*  
|               | *Larger studies with long-term follow-up needed to confirm findings and determine most effective laser parameters, sites and modes of application.*                                                                                                                                                                                                                                                                                                                                 |

**Glossary**

- **Near-IR light therapy** — Near-IR laser (also referred to as low-energy, low-level or cold laser) has low power with wavelengths of 600-1000 nm or greater. Near-IR laser is proposed for three main purposes: to promote wound healing, tissue repair, and the prevention of tissue death; to relieve inflammation and edema because of injuries or chronic diseases; and as an analgesic and a treatment for other neurological problems.

- **Far-IR light therapy** — Far-IR is a form of heat therapy delivered via heated saunas that exposes body tissues to slightly higher temperatures. Its purported medical benefits include treatment of health problems such as high blood pressure, congestive heart failure and rheumatoid arthritis.

**References**

**Professional society guidelines/other:**


**Peer-reviewed references:**


**Clinical trials**

Searched clinicaltrials.gov on April 13, 2016 using terms "IR therapy" and "light therapy." | Open Studies. 15 studies found, 5 relevant.


**CMS National Coverage Determination (NCDs):**


**Local Coverage Determinations (LCDs):**

L33571 Destruction of Internal Hemorrhoid(s) by INFRARED Coagulation (IRC) First Coast Service Options, Inc.
L34145  INFRARED Coagulation (IRC) of Hemorrhoids Noridian Healthcare Solutions, LLC

L34422  INFRARED Coagulation (IRC) of Hemorrhoids Palmetto GBA

L33825  INFRARED Heating Pad Systems CGS Administrators, LLC

CMS Medicare Coverage Database Web site. https://www.cms.gov/medicare-coverage-database/details/lcd-details.aspx?LCDId=34823&ver=6&CoverageSelection=Both&ArticleType=All&PolicyType=Final&s=All&KeyWord=tumor+treatment+field&KeyWordLookUp=Title&KeyWordSearchType=And&bc=gAAAABAAAAAAA %3d%3d& Accessed April 13, 2016

L34861  INFRARED Photocoagulation (IRC) of Hemorrhoids Novitas Solutions, Inc.

L30860 Destruction of Internal Hemorrhoid(s) by Infrared Coagulation (IRC) Florida (09101) 

L30862 Destruction of Internal Hemorrhoid(s) by Infrared Coagulation (IRC) Florida (09102) 

L31554 Infrared Coagulation (IRC) of Hemorrhoids South Carolina 

L30817 Infrared Photocoagulation (IRC) of Hemorrhoids District of Columbia, Delaware, Maryland, New Jersey, Pennsylvania (12901) 

L30817 Infrared Photocoagulation (IRC) of Hemorrhoids District of Columbia (12202) 

L30817 Infrared Photocoagulation (IRC) of Hemorrhoids Pennsylvania (12502) 

L30817 Infrared Photocoagulation (IRC) of Hemorrhoids District of Columbia (12201) 

L30817 Infrared Photocoagulation (IRC) of Hemorrhoids Pennsylvania (12501) 

L34350 Infrared Photocoagulation (IRC) of Hemorrhoids Louisiana (07202) 

L27513 Physical Medicine & Rehabilitation Services, Physical Therapy and Occupational Therapy District of Columbia, Pennsylvania

Commonly submitted codes

Below are the most commonly submitted codes for the service(s)item(s) subject to this policy. This is not an exhaustive list of codes. Providers are expected to consult the appropriate coding manuals and bill accordingly.

<table>
<thead>
<tr>
<th>CPT Code</th>
<th>Description</th>
<th>Comment</th>
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<tbody>
<tr>
<td>46930</td>
<td>Destruction of internal hemorrhoids by IR coagulation</td>
<td></td>
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<tr>
<td>97026</td>
<td>Application of a modality to 1 or more areas; IR</td>
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<thead>
<tr>
<th>ICD-10 Code</th>
<th>Description</th>
<th>Comment</th>
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<tbody>
<tr>
<td>K64.0</td>
<td>Hemorrhoids, first degree</td>
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<tr>
<td>K64.1</td>
<td>Hemorrhoids, second degree</td>
<td></td>
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<tr>
<td>M54.5</td>
<td>Low back pain</td>
<td></td>
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<tr>
<td>M54.9</td>
<td>Back pain</td>
<td></td>
</tr>
<tr>
<td>M79.1</td>
<td>Muscle pain</td>
<td></td>
</tr>
<tr>
<td>M79.601</td>
<td>Pain in right arm</td>
<td></td>
</tr>
<tr>
<td>M79.602</td>
<td>Pain in left arm</td>
<td></td>
</tr>
<tr>
<td>M79.603</td>
<td>Pain in arm, unspecified</td>
<td></td>
</tr>
<tr>
<td>M79.604</td>
<td>Pain in right leg</td>
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<tr>
<td>M79.605</td>
<td>Pain in left leg</td>
<td></td>
</tr>
<tr>
<td>M79.606</td>
<td>Pain in leg, specified</td>
<td></td>
</tr>
<tr>
<td>M79.609</td>
<td>Pain in unspecified limb</td>
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<tr>
<td>HCPCS Level II</td>
<td>Description</td>
<td>Comment</td>
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