



CLM 2020 Focus: Cannabis, Environmental, Insurance Fraud,  
Property, Subrogation, Claims & Litigation

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### **How to Manage the Wealth in Pain Management**

A provider's medical standard of care is moving away from opioid issuance. State Departments of Health are recommended alternative non-operative pain management options including injections, neural blocks, regenerative medicine and acupuncture among others.

#### Medical indications for Injections

Injections should be considered only after other appropriate therapeutic interventions have been tried. These include the use of nonsteroidal anti-inflammatory drugs (NSAIDs) and physical therapy. Injections can have diagnostic qualities and therapeutic value. Diagnostic injections and blocks are utilized to determine the location of injury and prepare a long-term plan of care.

Therapeutic injections can be ordered as pain management and be included in a lifecare plan.

#### I. Injections common in Soft Tissue Treatment and Length of Effectiveness

- A. Trigger Point Injections are a procedure used to treat painful areas of muscle that contain trigger points, or knots of muscle that form when muscles do not relax. During this procedure, a health care professional, using a small needle, injects a local anesthetic that sometimes includes a steroid into a trigger point (sterile saltwater is sometimes injected). With the injection, the trigger point is made inactive and the pain is alleviated. Usually, a brief course of treatment will result in sustained relief.

Photographs of trigger point injections used. Q/A - Therapeutic

- B. Facet injections / Facet joint block are also known as a zygapophysial joint block, the facet joint block is performed to determine whether a facet joint is a source of pain. Facet joints are located on the back of the spine, where one vertebra slightly overlaps another. These joints guide and restrict the spines movement.

*Video of Facet Injections used. Q/A - Diagnostic*

- C. In a nerve block, a doctor injects the area around the nerve with a numbing medicine, or anesthetic. Lidocaine is the anesthetic most commonly used. After a nerve block injection, you'll quickly have numbness with near-complete pain relief. It wears off after several hours.

*Video of Facet Injections used. Q/A - Diagnostic*

- D. Epidural steroid (ESI)

1. Epidural means "around the spinal cord." These shots include a steroid medicine, also called corticosteroid, and usually an anesthetic medicine, too. How effective they are isn't clear yet. Their effects seem to only last a short time and offer modest pain relief.
2. Epidural steroid injections are most commonly used in situations of radicular pain, which is a radiating pain that is transmitted away from the spine by an irritated spinal nerve. Irritation of a spinal nerve in the low back (lumbar radiculopathy), such as from lumbar spinal stenosis, cervical spinal stenosis, herniated disc, and foraminal encroachment, causes back pain that goes down the leg. Epidural injection is also used as a minimally invasive procedure to treat nerve compression in the neck (cervical spine), referred to as cervical radiculopathy, which causes pain.
3. The spinal cord rests in the spinal canal. The nerve roots branch out from the spinal cord at each level of a spinal vertebra (the bony building blocks of the spine). The cord is protected by cerebrospinal fluid (CSF), which serves as a shock absorber for the cord. The CSF is held in place by a membrane with several layers, one of which is called the dura, from the Greek for tough (think of "durable"). The Greek word "epi" means "outside of." So, the epidural space is outside of this tough membrane. During an epidural steroid injection, a needle and syringe are used to enter the epidural space and deposit small amounts of long-lasting steroids around the inflamed spinal nerve. A fluoroscope (a viewing instrument using X-rays) is used to visualize the local anatomy during the injection. The epidural steroid injection specifically targets the locally inflamed area and treats it with a maximal

number of steroids, thereby minimizing exposure of the rest of the body to the steroids.

4. Recovery from an epidural steroid injection is typically within hours of the injection. If anesthetic is administered with the steroid, there can be hours of residual numbness of the nerves that were anesthetized.

Video of Facet Injections used. Q/A - Therapeutic

- I. Medications used

Anesthetics are used to reduce or prevent pain. The anesthetic is typically provided as a topical on the skin. Then analgesics such as lidocaine are often used along with the injections to numb injection sites internally. Then steroids are used as anti-inflammatories for the soft tissues. Often the medications are single use and the waste unnecessarily high. The medications will be recommended for long term use, but specifically steroids include risks of long-term use include degradation of disc material.

- II. Who can Perform Injections/Blocks?

Many States have MD/DO and Pain Management clinic statutes. Fla. Statutes. Section 458.3265 and 459.0137 for just a few examples.

Physician Extenders such as Advanced Registered Nurse Practitioners and Certified Registered Nurse Anesthetists (ARNPs / CRNAs). In 2001, President Clinton signed into law a rule that permitted states to "opt out" of the Centers for Medicare and Medicaid Services' (CMS) requirement for nurse anesthetists to be supervised by any physician. Since then, 17 states have adopted this rule. While it was originally intended to help rural areas improve access to care, the opt out rule essentially supports any hospital or organization that seeks to make a profit or cut costs by allowing nurse anesthetists to function as physicians.

With the implementation of sweeping health care regulations under the Affordable Care Act (ACA, also popularly known as Obamacare), the future of nurses and other professionals has been empowered. In fact, it has been proposed that medical training may be reduced by 30%, which will in their minds equalize training between nonphysicians and physicians. In 2010, the Federal Trade Commission (FTC) issued an opinion exerting their power to empower

CRNAs with unlimited practice, with threats to opposing parties. In the 2013 proposed physician payment rule, CMS is proposing that CRNAs may perform interventional pain management services.

### III. Regenerative Medication

Regenerative medicines are cutting-edge therapies that use chemistry, medicine, robotics, biology, computer science, genetics, and engineering to construct a biologically compatible structure for many different tissues found in the body. Two common trends include Platelet Rich Plasma and Stem Cell therapy. Blood products such as PRP fall under the purview of FDA's Center for Biologics Evaluation and Research (CBER). CBER is responsible for regulating human cells, tissues, and cellular and tissue-based products. The regulatory process for these products is described in the FDA's 21 CFR 1271 of the Code of Regulations. Under these regulations, certain products including blood products such as PRP are exempt and therefore do not follow the FDA's traditional regulatory pathway that includes animal studies and clinical trials. The 510(k) application is the pathway used to bring PRP preparation systems to the market. The 510(k) application allows devices that are "substantially equivalent" to a currently marketed device to come to the market. There are numerous PRP preparation systems on the market today with FDA clearance; however, nearly all these systems have 510(k) clearance for producing platelet-rich preparations intended to be used to mix with bone graft materials to enhance bone graft handling properties in orthopedic practices. The use of PRP outside this setting, for example, an office injection, would be considered "off label." Clinicians are free to use a product off-label if certain responsibilities are met. Per CBER, when the intent is the practice of medicine, clinicians "have the responsibility to be well informed about the product, to base its use on firm scientific rationale and on sound medical evidence, and to maintain records of the product's use and effects." Finally, despite PRP being exempted, the language in 21 CFR 1271 has caused some recent concern over activated PRP; however, to date, the FDA has

not attempted to regulate activated PRP. Clinicians using activated PRP should be mindful of these concerns and continued to stay informed

Platelet Rich Plasma Therapy (or PRP) is blood plasma that contains concentrated amounts of platelets and growth factors. The concentrated platelets are rich in bioactive proteins and they work with the growth factors to trigger and accelerate tissue repair.

Stem cell therapy is a medical treatment that involves the delivery of stem cells to restore cartilage to an injured knee, according to the National Institutes of Health. The treatment is applied to articular cartilage lesions caused by focal defects, trauma or osteoarthritis. The stem cells used for this therapy include mesenchymal stem cells derived from tissue sources such as bone marrow, adipose tissue, umbilical cord blood, muscle and peripheral blood.

The most common joint injuries treated with stem cell therapy include pes anserine bursitis, meniscus tears, biceps femoris insertional tendinopathy, cartilage damage, and arthritis or osteoarthritis, as reported by Stem Cell Arts. A stem cell injection is an alternative treatment to surgery or joint replacement. Patients who receive stem cell therapy to treat knee injuries and osteoarthritis avoid the rehabilitation process that normally accompanies surgery or replacement, according to Rehabilitation and Pain Specialists. Stem cell therapy delivers stem cells to an area that needs an additional number of stem cells to heal injured bone, ligaments, tendons and tissues

#### IV. Expense / Case Value (Examples)

Standard Insurance with coverages tied to fee schedule limitations are often not the focus for long term pain management options. Rather, extended coverages and commercial lines with personal injury provisions are often the focus. Pain management is provided three times a year or more for a lifetime pursuant to the mortality tables.

V. Mortality Table provided.

Treatment is often provided for little to no up-front payment during a claim managed by a lawyer. Letters of Protection are signed, but then inflated bills submitted without basis to usual or customary payments within the community. Payments later made on outstanding billing after settlement are at 40-60% of the amounts charged with reduced amounts.

Example LOPs provided.