



General

Guideline Title

Lower extremity injury medical treatment guidelines.

Bibliographic Source(s)

Colorado Division of Workers' Compensation. Lower extremity injury medical treatment guidelines. Denver (CO): Colorado Division of Workers' Compensation; 2016 Mar 16. 211 p. [691 references]

Guideline Status

This is the current release of the guideline.

This guideline updates a previous version: Colorado Division of Workers' Compensation. Lower extremity injury medical treatment guidelines. Denver (CO): Colorado Division of Workers' Compensation; 2009 Jun 24. 136 p.

This guideline meets NGC's 2013 (revised) inclusion criteria.

Regulatory Alert

FDA Warning/Regulatory Alert

Note from the National Guideline Clearinghouse: This guideline references a drug(s) for which important revised regulatory and/or warning information has been released.

- [August 31, 2016 – Opioid pain and cough medicines combined with benzodiazepines](#) : A U.S. Food and Drug Administration (FDA) review has found that the growing combined use of opioid medicines with benzodiazepines or other drugs that depress the central nervous system (CNS) has resulted in serious side effects, including slowed or difficult breathing and deaths. FDA is adding Boxed Warnings to the drug labeling of prescription opioid pain and prescription opioid cough medicines and benzodiazepines.
- [March 22, 2016 – Opioid pain medicines](#) : The U.S. Food and Drug Administration (FDA) is warning about several safety issues with the entire class of opioid pain medicines. These safety risks are potentially harmful interactions with numerous other medications, problems with the adrenal glands, and decreased sex hormone levels. They are requiring changes to the labels of all opioid drugs to warn about these risks.

Recommendations

Major Recommendations

Note from the National Guideline Clearinghouse (NGC): This summary includes the treatment recommendations of the guideline. Refer to the original guideline document for additional information on initial evaluation and diagnostic procedures for patients with lower extremity injury and for further descriptions of the therapies discussed below.

Therapeutic Procedures—Non-operative

Before initiation of any therapeutic procedure, the authorized treating provider, employer, and insurer must consider these four important issues in the care of the injured worker.

First, patients undergoing therapeutic procedure(s) should be released or returned to modified, restricted duty during their rehabilitation at the earliest appropriate time. Refer to the "Return to Work" section below and in the original guideline document for detailed information.

Second, cessation and/or review of treatment modalities should be undertaken when no further significant subjective or objective improvement in the patient's condition is noted. If patients are not responding within the recommended duration periods, alternative treatment interventions, further diagnostic studies or consultations should be pursued.

Third, providers should provide and document patient education. Functional progression is expected through prescribed activity such as neuromuscular and postural re-education/re-patterning exercises. Before diagnostic tests or referrals for invasive treatment take place, the patient should be able to clearly articulate the goals of the intervention, the general side effects and associated risks, and his or her agreement with the expected treatment plan.

Last, formal psychological or psychosocial evaluation should be performed on patients not making expected progress within 6 to 12 weeks following injury and whose subjective symptoms do not correlate with objective signs and tests. Home therapy is an important component of therapy and may include active and passive therapeutic procedures as well as other modalities to assist in alleviating pain, swelling, and abnormal muscle tone.

The following procedures are listed in alphabetical order.

Acupuncture

When acupuncture has been studied in randomized clinical trials, it is often compared with sham acupuncture and/or no acupuncture (usual care). The differences between true acupuncture and usual care have been moderate, but clinically important. These differences can be partitioned into two components: non-specific effects and specific effects. Non-specific effects include patient beliefs and expectations, attention from the acupuncturist, administration of acupuncture in a relaxing setting, and other components of what is often called the placebo effect. Specific effects refer to any additional effects which occur in the same setting of expectations and attention, but they are attributable to the penetration of the skin in the specific, classic acupuncture points on the surface of the body by the needles themselves.

Clinical trials of acupuncture typically enroll participants who are interested in acupuncture, and who may respond to some of the non-specific aspects of the intervention more than patients who have no interest in or desire for acupuncture. The non-specific effects of acupuncture may not be produced in patients who have no wish to be referred for it. Another study provides good evidence that true acupuncture at traditional meridians is marginally better than sham acupuncture with blunt needles in reducing pain, but effects on disability are unclear. In these studies, 5 to 15 treatments were provided. Comparisons of acupuncture and sham acupuncture have been inconsistent, and the advantage of true over sham acupuncture has been small in relation to the advantage of sham over no acupuncture. A recent study of acupuncture use for knee osteoarthritis (OA) casts doubt on the actual biological effects of acupuncture versus the effect of positive provider patient visits.

Acupuncture is recommended for subacute or chronic pain patients who are trying to increase function and/or decrease medication usage and have an expressed interest in this modality. It is also recommended for subacute or acute pain for patients who cannot tolerate non-steroidal anti-inflammatory drugs (NSAIDs) or other medications.

Acupuncture is not the same procedure as dry needling for coding purposes; however, some acupuncturists may use acupuncture treatment for myofascial trigger points. Dry needling is performed specifically on myofascial trigger points. Refer to "Trigger Point Injections" and "Dry Needling Treatment" in the original guideline document.

Acupuncture should generally be used in conjunction with manipulative and physical therapy/rehabilitation. Credentialed practitioners with experience in evaluation and treatment of chronic pain patients must perform evaluations prior to acupuncture treatments.

There is good evidence that, in people with osteoarthritis of the knee or hip, the effects of true needle acupuncture treatment relative to sham acupuncture may be too small to be perceived by participants as beneficial. Therefore, true needle acupuncture may not actually result in significant, clinically relevant functional improvement or significant pain reduction. Thus, there is strong evidence that acupuncture is not effective for

osteoarthritis pain relief and it is not generally recommended. It may be appropriate in cases where arthroplasty is being delayed and patients request acupuncture for temporary relief.

Indications: All patients being considered for acupuncture treatment should have subacute or chronic pain (lasting approximately 3 to 4 weeks depending on the condition) and meet the following criteria:

- They should have participated in an initial active therapy program and
- They should show a clear preference for this type of care or previously have benefited from acupuncture and
- They must continue to be actively engaged in physical rehabilitation therapy and return to work.

Acupuncture

Acupuncture is the insertion and removal of filiform needles to stimulate acupoints (acupuncture points). Needles may be inserted, manipulated and retained for a period of time. Acupuncture can be used to reduce pain, reduce inflammation, increase blood flow, increase range-of-motion, decrease the side effect of medication-induced nausea, promote relaxation in an anxious patient, and reduce muscle spasm. Indications include joint pain, joint stiffness, soft tissue pain and inflammation, paresthesia, post-surgical pain relief, muscle spasm, and scar tissue pain.

Acupuncture with Electrical Stimulation

Acupuncture with electrical stimulation is the use of electrical current (micro-ampere or milli-ampere) on the needles at the acupuncture site. It is used to increase effectiveness of the needles by continuous stimulation of the acupoint. Physiological effects (depending on location and settings) can include endorphin release for pain relief, reduction of inflammation, increased blood circulation, analgesia through interruption of pain stimulus, and muscle relaxation. It is indicated to treat chronic pain conditions, radiating pain along a nerve pathway, muscle spasm, inflammation, scar tissue pain, and pain located in multiple sites.

Total Time Frames for Acupuncture and Acupuncture with Electrical Stimulation

Time frames are not meant to be applied to each of the above sections separately. The time frames are to be applied to all acupuncture treatments regardless of the type or combination of therapies being provided. Refer to the original guideline document for time to produce effect, frequency, and optimum and maximum duration of treatments.

Any of the acupuncture treatments may extend longer if objective functional gains can be documented and when symptomatic benefits facilitate progression in the patient's treatment program. Treatment beyond 14 treatments must be documented with respect to need and ability to facilitate positive symptomatic or functional gains. Such care should be re-evaluated and documented with each series of treatments.

Other Acupuncture Modalities

Acupuncture treatment is based on individual patient needs and therefore treatment may include a combination of procedures to enhance treatment effect. Other procedures may include the use of heat, soft tissue manipulation/massage, and exercise. Refer to "Therapy-Active" and "Therapy-Passive" below for a description of these adjunctive acupuncture modalities and time frames.

Biofeedback

Biofeedback is a form of behavioral medicine that helps patients learn self-awareness and self-regulation skills for the purpose of gaining greater control of their physiology, such as muscle activity, brain waves, and measures of autonomic nervous system activity. Stress-related psychophysiological reactions may arise as a reaction to organic pain and in some cases may cause pain. Electronic instrumentation is used to monitor the targeted physiology and then displayed or fed back to the patient visually, auditorially, or tactilely, with coaching by a biofeedback specialist. There is good evidence that biofeedback or relaxation therapy is equal in effect to cognitive behavioral therapy for chronic low back pain. There is no evidence of the effect of electromyogram (EMG)-biofeedback on knee OA. Therefore, it is *not recommended*. Indications for biofeedback include cases of musculoskeletal injury, in which muscle dysfunction or other physiological indicators of excessive or prolonged stress response affects and/or delays recovery. Other applications include training to improve self-management of pain, anxiety, panic, anger or emotional distress, opioid withdrawal, insomnia/sleep disturbance, and other central and autonomic nervous system imbalances. Biofeedback is often utilized for relaxation training. Mental health professionals may also utilize it as a component of psychotherapy, where biofeedback and other behavioral techniques are integrated with psychotherapeutic interventions. Biofeedback is often used in conjunction with physical therapy or medical treatment.

Refer to the original guideline document for time to produce effect, frequency, and optimum and maximum duration of treatments.

Bone Growth Stimulators

Electrical

Pre-clinical and experimental literature has shown a stimulatory effect of externally applied electrical fields on the proliferation and calcification of osteoblasts and periosteal cells. There is good evidence that, in the setting of acute tibial shaft fractures, pulsed electromagnetic field devices do not reduce the rate of secondary surgical procedures in the first twelve months following the acute fracture. Therefore, the use of these devices is *not recommended*.

Low-intensity Pulsed Ultrasound (LIPUS)

There is strong evidence that LIPUS does not have clinical efficacy in returning fracture patients to normal activities, and that the estimates of effectiveness in accelerating radiographic fracture healing are likely to be biased and inaccurate. There is no evidence of the effect of LIPUS, high-intensity focused ultrasound (HIFUS) and extracorporeal shockwave therapies (ESWT) as part of the treatment for acute fractures in adults. Therefore, the use of external bone growth stimulation in the setting of acute fractures in high risk patients requires prior authorization.

Education/Informed Decision Making

Education and informed decision making of the patient and family, as well as the employer, insurer, policy makers and the community should be the primary emphasis in the treatment of shoulder pain and disability. Informed decision making is the hallmark of a successful treatment plan. In most cases, the continuum of treatment from the least invasive to the most invasive (e.g., surgery) should be discussed. The intention is to find the treatment along this continuum which most completely addresses the condition.

Patients should identify their personal functional goals of treatment at the first visit. It is recommended that specific individual goals are articulated at the beginning of treatment as this is likely to lead to increased patient satisfaction above that achieved from improvement in pain or other physical function. Progress toward the individual functional goals identified should be addressed at follow up visits and throughout treatment by other members of the health care team as well as the authorized physicians.

Documentation of this process should occur whenever diagnostic tests or referrals from the authorized treating physician are contemplated. The informed decision making process asks the patients to set their personal functional goals of treatment, describe their current health status and any concerns they have regarding adhering to the diagnostic or treatment plan proposed. The provider should clearly describe the following:

- The expected functional outcomes from the proposed treatment, or expected results and plan of action if diagnostic tests are involved
- Any side effects and risks to the patient
- Required post treatment rehabilitation time and impact on work, if any
- Alternative therapies or diagnostic testing

Before diagnostic tests or referrals for invasive treatment take place, the patient should be able to clearly articulate the goals of the intervention, the general side effects and risks associated with it and their decision regarding compliance with the suggested plan. There is some evidence that information provided only by video is not sufficient education. Practitioners must develop and implement an effective strategy and skills to educate patients, employers, insurance systems, policy makers, and the community as a whole. An education-based paradigm should always start with providing reassuring information to the patient and informed decision making. More in-depth education currently exists within a treatment regimen employing functional restoration, prevention, and cognitive behavioral techniques. Patient education and informed decision making should facilitate self-management of symptoms and prevention.

Extracorporeal Shock Wave Therapy (ESWT)

ESWT delivers an externally applied acoustic pulse to the plantar fascia.

High energy ESWT is delivered in one session and may be painful, requiring some form of anesthesia. Conscious sedation is *not recommended*.

The procedure may be performed with local blocks. There is good evidence from one high quality trial that high intensity ESWT (0.25 mJ/mm²) is more effective than sham ESWT for improving pain and function in chronic plantar fasciitis which has not responded to conservative treatment after 6 months of symptoms. There is also some evidence from one adequate trial that high dose shock wave produces successful outcomes similar to those for endoscopic plantar fascia release in patients with persistent plantar fasciopathy which has not responded to more conservative treatment. However, two flawed meta-analyses failed to provide evidence that ESWT, regardless of energy level, produces a clinically meaningful reduction in pain or increase in function when compared to placebo for patients with plantar fasciitis lasting 6 months or more. While both meta-analyses did find a benefit for ESWT, the effect did not reach the level of clinical significance and provided conflicting evidence for which energy level is more effective. However, there is good evidence that plantar fascia specific stretching as initial treatment is more effective than radial ESWT in reducing pain and increasing function. Therefore, only ESWT at high intensity (0.25 mJ/mm²) may be considered in patients who have failed 6 months of conservative treatment, including stretching, physical therapy, orthoses, ice, and NSAIDs, and have significant functional deficits. This may be

attempted for a maximum of 3 sessions spaced at least a week apart. ESWT may be a cost-effective alternative to plantar fascial release or a final non-invasive treatment option before surgery. There is no evidence for extracorporeal shockwave therapies (ESWT) as part of the treatment for acute fractures in adults. An adequate systematic review failed to provide evidence that ESWT is superior to sham ESWT for Achilles tendinopathy. This review examined the only two studies in the past 10 years that had adequate blinding of participants. However, a clinically important effect has not been ruled out, and future research may change the unbiased estimate of the effect of ESWT. Additionally, a single randomized controlled trial does provide some evidence that in patients with insertional Achilles tendinopathy who have no calcification of the tendon at the calcaneus, three sessions of a moderate dose (flux density of 0.12 ml/mm²) is likely to be more successful than a 12 week program of eccentric loading exercise. As such, providers should be free to add ESWT to their treatment options for Achilles tendinopathy.

Indications: Patients who have failed 6 months of standard therapy for plantar fasciitis and have significant functional deficits should be considered for ESWT. These patients should meet the indications for surgery. Tarsal tunnel syndrome should be ruled out. Peripheral vascular disease, lower extremity neuropathy, and diabetes are all relative contraindications. Diagnostic testing may be needed to rule out these conditions. ESWT may also be considered for those patients who have failed conservative treatment for Achilles tendinopathy.

Refer to the original guideline document for time to produce effect, frequency, and optimum and maximum duration of treatments.

Injections—Therapeutic

Description: Therapeutic injection procedures may play a significant role in the treatment of patients with lower extremity pain or pathology. Therapeutic injections involve the delivery of anesthetic and/or anti-inflammatory medications to the painful structure. Therapeutic injections have many potential benefits. Ideally, a therapeutic injection will: (a) reduce inflammation in a specific target area; (b) relieve secondary muscle spasm; (c) allow a break from pain; and (d) support therapy directed to functional recovery. Diagnostic and therapeutic injections should be used early and selectively to establish a diagnosis and support rehabilitation. If injections are overused or used outside the context of a monitored rehabilitation program, they may be of significantly less value.

Caution should be used when ordering four or more steroid injections total for all anatomic sites in one year.

Diagnostic injections are procedures which may be used to identify pain generators or pathology. For additional specific clinical indications, see "Specific Lower Extremity Injury Diagnosis, Testing and Treatment Procedures" section in the original guideline document.

Contraindications: General contraindications include local or systemic infection, bleeding disorders, allergy to medications used and patient refusal. Specific contraindications may apply to individual injections.

Steroid Injections

Steroid Injections are generally accepted, well-established procedures that can be performed as analgesic or anti-inflammatory procedures. There is good evidence that steroid injection in the setting of knee osteoarthritis produces rapid but short-lasting pain relief compared to placebo, likely to last at least one week but not likely to last 4 weeks or longer. There is good evidence for a small to moderate reduction in pain from corticosteroid injection, whether performed under ultrasound guidance or by palpation alone. Tibial nerve blocks (heel blocks) do not add benefit to the procedure. It is unclear whether factors such as the specific corticosteroid, the injection approach (e.g., medial vs. posterior), the injection target (e.g., parallel to the plantar fascia vs. into the plantar fascia), or mixing of local anesthetic with the steroid influence outcomes.

Steroid injections to the Achilles tendon should generally be avoided since this is a risk for later rupture. Therefore, steroid injections are *not recommended* for any pathology of the Achilles tendon.

Complications: Safety concerns regarding steroid injection of the heel exist, including plantar fascia rupture and heel pad atrophy. Steroid injection under significant pressure should be avoided as the needle may be penetrating the tendon, and injection into the tendon could cause tendon breakdown, degeneration, or rupture. Injections should be minimized for patients under 30 years of age. General complications of injections may include transient neurapraxia, nerve injury, infection, hematoma, glucose elevation, and endocrine changes. The majority of diabetic patients will experience an increase in glucose following steroid injections. (Refer to specific sections in the original guideline document for additional information on complications of steroid injection.)

Refer to the original guideline document for time to produce effect, frequency, and optimum and maximum duration of treatments.

Soft Tissue Injections

Soft tissue injections include bursa and tendon insertions. Injections under significant pressure should be avoided as the needle may be penetrating the tendon. Injection into the tendon can cause tendon degeneration, tendon breakdown, or rupture. Injections should be minimized for patients under 30 years of age. When performing tendon insertion injections, the risk of tendon rupture should be discussed with the patient and the need

for restricted duty emphasized.

Refer to the original guideline document for time to produce effect, frequency, and optimum and maximum duration of treatments.

Stem Cell Injections

The purpose of stem cell therapy is to supply mesenchymal stem cells to a site of injury. The cells may then differentiate into cells that may aid recovery.

To date the U.S Food and Drug Administration (FDA) has only approved one stem cell product, a cord blood-derived product for use in specific disorders involving the blood forming system only. Numerous trials are currently in process or have not been published regarding the use of stem cells from bone marrow aspirate or demineralized bone matrix. The only clear effects are on small bone deficits. They are considered to be experimental and thus are *not recommended* for delayed union or nonunion of long bone fractures.

There is some evidence from one study that, in the setting of core decompression, the use of bone marrow derived mesenchymal stem cells, taken from subtrochanteric marrow, cultured in vitro for two weeks, and implanted back into the necrotic lesion, greatly reduces the rate of progression of the disease process over the following five years. There is also some evidence that the procedure similarly reduces the need for total hip replacement. It is not known how this study related to non-cultured stem cells. Core decompression has been tried with mesenchymal stem cells and bone marrow derived cells. However, currently stem cells cannot be cultured in the United States. Due to differing techniques and study methodologies, these procedures continue to be considered experimental and are *not generally recommended*.

Platelet Rich Plasma (PRP)

PRP injections are intended to augment soft tissue healing. Blood is obtained from the patient, centrifuged to increase the platelet content and re-injected into the injury site. There is some evidence that, in the setting of total knee arthroplasty, intraoperative use of PRP can reduce blood loss, improve levels of postoperative hemoglobin, and reduce the need for blood transfusions by the third postoperative day. There is also some evidence that PRP theoretically may improve pain control and promote earlier return to function. Therefore it may be used in total knee arthroplasty.

PRP is *not generally recommended*. It may be considered in unusual circumstances for cases which meet the following three criteria:

- Tendon damage or osteoarthritis and
- Non-responsiveness to appropriate conservative measures and
- The next level of guideline-consistent therapy would involve an invasive procedure with risk of significant complications.

If PRP is found to be indicated in these select patients, the first injection may be repeated twice when significant functional benefit is reported but the patient has not returned to full function. Steroid injections prior to use of PRP are believed to lower the chance of healing. Generally, PRP injections should not be used for at least 2 months following a steroid injection.

Viscosupplementation/Intracapsular Acid Salts

There is inadequate evidence that hyaluronic acid is more effective than saline for treatment of ankle osteoarthritis. Hyaluronic acid injections are, therefore, *not recommended* for ankle osteoarthritis due to the small effect size documented in knee conditions and the lack of evidence supporting its use in the ankle. Therefore, the patient and treating physician should identify functional goals and the likelihood of achieving improved ability to perform activities of daily living (ADL) or work activities with injections versus other treatments. The patient should agree to comply with the treatment plan including home exercise. These injections may be considered an alternative in patients who have failed non-operative treatment and for whom surgery is not an option, particularly if non-steroidal anti-inflammatory drug treatment is contraindicated or has been unsuccessful.

Viscosupplementation's efficacy beyond 6 months is not well-established. Prior authorization is required to approve product choice and for repeat series of injections. Due to lack of efficacy, viscosupplementation for knee or ankle is *not recommended* and requires prior authorization. It may be used for patients with significant functional deficits who are not eligible for or wish to delay arthroplasty.

Viscosupplementation is *not recommended* for hip arthritis given the probable superiority of corticosteroid injections. In rare cases a patient with significant hip osteoarthritis who does not qualify for surgical intervention may try viscosupplementation. It should be done with ultrasound or fluoroscopic guidance and will not necessarily require a series of three injections. The patient may choose to have repeat injections when the first injection was successful.

Refer to the original guideline document for time to produce effect, frequency, and optimum and maximum duration of treatments.

Prolotherapy (Also Known as Sclerotherapy)

Prolotherapy consists of peri-articular injections of hypertonic dextrose with or without phenol with the goal of inducing an inflammatory response that will recruit cytokine growth factors involved in the proliferation of connective tissue.

The evidence in support of prolotherapy is insufficient and therefore, its use is *not recommended* in lower extremity injuries.

Trigger Point Injections and Dry Needling

Although generally accepted, trigger point injections have only rare indications in the treatment of lower extremity disorders. Therefore, the Division does *not recommend* their routine use in the treatment of lower extremity injuries.

Description: Trigger point treatment can consist of dry needling or injection of local anesthetic with or without corticosteroid into highly localized, extremely sensitive bands of skeletal muscle fibers that produce local and referred pain when activated. Medication is injected in a four-quadrant manner in the area of maximum tenderness. Injection and dry needling efficacy can be enhanced if treatments are immediately followed by myofascial therapeutic interventions, such as vapo-coolant spray and stretch, ischemic pressure massage (myotherapy), specific soft tissue mobilization and physical modalities.

There is no indication for conscious sedation for patients receiving trigger point injections or dry needling. The patient must be alert to help identify the site of the injection.

Indications: Trigger point injections and dry needling may be used to relieve myofascial pain and facilitate active therapy and stretching of the affected areas. They are to be used as an adjunctive treatment in combination with other treatment modalities such as active therapy programs. Trigger point injections should be utilized primarily for the purpose of facilitating functional progress. Patients should continue in an aggressive aerobic and stretching therapeutic exercise program as tolerated, while undergoing intensive myofascial interventions. Myofascial pain is often associated with other underlying structural problem. Any abnormalities need to be ruled out prior to injection.

Trigger point injections and dry needling are indicated in patients with consistently observed, well circumscribed trigger points. This demonstrates a local twitch response, characteristic radiation of pain pattern and local autonomic reaction, such as persistent hyperemia following palpation. Generally, neither trigger point injections nor dry needling are necessary unless consistently observed trigger points are not responding to specific, non-invasive, myofascial interventions within approximately a 6-week time frame. However, both trigger point injections and dry needling may be occasionally effective when utilized in the patient with immediate, acute onset of pain or in a postoperative patient with persistent muscle spasm or myofascial pain.

Complications: Potential but rare complications of trigger point injections and dry needling include infection, anaphylaxis, penetration of viscera, neurapraxia, and neuropathy. If corticosteroids are injected in addition to local anesthetic, there is a risk of developing local myopathy. Severe pain on injection suggests the possibility of an intraneural injection, and the needle should be immediately repositioned.

Refer to the original guideline document for time to produce effect, frequency, and optimum and maximum duration of treatments.

Botulinum Toxin Injections

Description: Used to temporarily weaken or paralyze muscles. May reduce muscle pain in conditions associated with spasticity, dystonia, or other types of painful muscle spasm. Electromyography (EMG) needle guidance may permit more precise delivery of botulinum toxin to the target area.

The evidence supports injections into the gastrocnemius-soleus complex. There is insufficient evidence and no plausible physiologic theory to support a botulinum toxin injection into the plantar fascia. Therefore, it is *not recommended*.

Complications: Rare systemic effects include flu-like syndrome, and weakening of distant muscles.

Refer to the original guideline document for time to produce effect, frequency, and optimum and maximum duration of treatments.

Interdisciplinary Rehabilitation Programs

This is the gold standard of treatment for individuals who have not responded to less intensive modes of treatment. There is good evidence that interdisciplinary programs that include screening for psychological issues, identification of fear-avoidance beliefs and treatment barriers, and establishment of individual functional and work goals will improve function and decrease disability. These programs should assess the impact of pain and suffering on the patient's medical, physical, psychological, social, and/or vocational functioning. In general, interdisciplinary programs evaluate and treat multiple and sometimes irreversible conditions, including, but not limited to: painful musculoskeletal, neurological, and other chronic pain conditions and psychological issues; drug dependence, abuse, or addiction; high levels of stress and anxiety; failed surgery; and pre-existing or latent psychopathology. The number of professions involved on the team in a chronic pain program may vary due to the complexity of the needs of the person served. The Division recommends consideration of referral to an interdisciplinary program within 6 months post-injury in

patients with delayed recovery, unless successful surgical interventions or other medical and/or psychological treatment complications intervene.

Chronic pain patients need to be treated as outpatients within a continuum of treatment intensity. Outpatient chronic pain programs are available with services provided by a coordinated interdisciplinary team within the same facility (formal) or as coordinated among practices by the authorized treating physician (informal). Formal programs are able to provide a coordinated, high-intensity level of services and are recommended for most chronic pain patients who have received multiple therapies during acute management.

Patients with addiction problems, high-dose opioid use, or abuse of other drugs may require inpatient and/or outpatient chemical dependency treatment programs before or in conjunction with other interdisciplinary rehabilitation. Guidelines from the American Society of Addiction Medicine are available and may be consulted relating to the intensity of services required for different classes of patients in order to achieve successful treatment.

Informal interdisciplinary pain programs may be considered for patients who are currently employed, those who cannot attend all-day programs, those with language barriers, or those living in areas not offering formal programs. Before treatment has been initiated, the patient, physician, and insurer should agree on treatment approach, methods, and goals. Generally, the type of outpatient program needed will depend on the degree of impact the pain has had on the patient's medical, physical, psychological, social, and/or vocational functioning.

When referring a patient for formal outpatient interdisciplinary pain rehabilitation, an occupational rehabilitation program, or an opioid treatment program, the Division recommends the program meets the criteria of the Commission on Accreditation of Rehabilitation Facilities (CARF).

Inpatient pain rehabilitation programs are rarely needed but may be necessary for patients with any of the following conditions: (a) high risk for medical instability; (b) moderate-to-severe impairment of physical/functional status; (c) moderate-to-severe pain behaviors; (d) moderate impairment of cognitive and/or emotional status; (e) dependence on medications from which he/she needs to be withdrawn; and (f) the need for 24-hour supervised nursing.

Whether formal or informal programs, they should be comprised of the following dimensions:

- Communication
- Documentation
- Treatment modalities
- Therapeutic exercise programs
- Return to work
- Patient education
- Psychosocial evaluation and treatment
- Vocational assistance

Interdisciplinary programs are characterized by a variety of disciplines that participate in the assessment, planning, and/or implementation of the treatment program. These programs are for patients with greater levels of perceived disability, dysfunction, de-conditioning, and psychological involvement. Programs should have sufficient personnel to work with the individual in the following areas: behavioral, functional, medical, cognitive, pain management, psychological, social, and vocational.

Formal Interdisciplinary Rehabilitation Programs

Interdisciplinary Pain Rehabilitation

An Interdisciplinary Pain Rehabilitation Program provides outcome-focused, coordinated, goal-oriented interdisciplinary team services to measure and improve the functioning of persons with pain and encourage their appropriate use of health care system and services. The program can benefit persons who have limitations that interfere with their physical, psychological, social, and/or vocational functioning. The program shares information about the scope of the services and the outcomes achieved with patients, authorized providers, and insurers.

The interdisciplinary team maintains consistent integration and communication to ensure that all interdisciplinary team members are aware of the plan of care for the patient, are exchanging information, and implement the plan of care. The team members make interdisciplinary team decisions with the patient and then ensure that decisions are communicated to the entire care team.

The Medical Director of the pain program should ideally be board certified in pain management. Alternatively, he/she should be board certified in his/her specialty area and have completed a one-year fellowship in interdisciplinary pain medicine or palliative care recognized by a national board. As a final alternative, he or she should have two years of experience in an interdisciplinary pain rehabilitation program. Teams that assist in the accomplishment of functional, physical, psychological, social, and vocational goals must include: a medical director, pain team physician(s), who should preferably be board certified in an appropriate specialty, and a pain team psychologist. Professionals from other disciplines on the team may

include, but are not limited to: a biofeedback therapist, an occupational therapist, a physical therapist, a registered nurse (RN), a case manager, an exercise physiologist, a psychologist, a psychiatrist, and/or a nutritionist.

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Occupational Rehabilitation

This is a formal interdisciplinary program addressing a patient's employability and return to work. It includes a progressive increase in the number of hours per day in which a patient completes work simulation tasks until the patient can tolerate a full work day. A full work day is case specific and is defined by the previous employment of the patient. Safe workplace practices and education of the employer and family and/or social support system regarding the person's status should be included. This is accomplished by addressing the medical, psychological, behavioral, physical, functional, and vocational components of employability and return to work.

There is some evidence that an integrated care program, consisting of workplace interventions and graded activity teaching that pain need not limit activity, is effective in returning patients with chronic low back pain to work, even with minimal reported reduction of pain.

The occupational medicine rehabilitation interdisciplinary team should, at a minimum, be comprised of a qualified medical director who is board certified with documented training in occupational rehabilitation; team physicians having experience in occupational rehabilitation; an occupational therapist; and a physical therapist. As appropriate, the team may also include any of the following: chiropractor, an RN, a case manager, a psychologist, a vocational specialist, or a certified biofeedback therapist.

Refer to the original guideline document for time to produce effect, frequency, and optimum and maximum duration of treatments.

Opioid/Chemical Treatment Programs

Refer to the Division's [Chronic pain disorder medical treatment guidelines](#) .

Informal Interdisciplinary Rehabilitation Program

A coordinated interdisciplinary pain rehabilitation program is one in which the authorized treating physician coordinates all aspects of care. This type of program is similar to the formal programs in that it is goal-oriented and provides interdisciplinary rehabilitation services to manage the needs of the patient in the following areas: (a) functional, (b) medical, (c) physical, (d) psychological, (e) social, and (f) vocational.

This program is different from a formal program in that it involves lower frequency and intensity of services/treatment. Informal rehabilitation is geared toward those patients who do not need the intensity of service offered in a formal program or who cannot attend an all-day program due to employment, daycare, language, or other barriers.

Patients should be referred to professionals experienced in outpatient treatment of chronic pain. The Division recommends the authorized treating physician consult with physicians experienced in the treatment of chronic pain to develop the plan of care. Communication among care providers regarding clear objective goals and progress toward the goals is essential. Employers should be involved in return to work and work restrictions, and the family and/or social support system should be included in the treatment plan. Professionals from other disciplines likely to be involved include: a biofeedback therapist, an occupational therapist, a physical therapist, an RN, a psychologist, a case manager, an exercise physiologist, a psychiatrist, and/or a nutritionist.

Refer to the original guideline document for time to produce effect, frequency, and optimum and maximum duration of treatments.

Jobsite Alteration

Early evaluation and training of body mechanics are essential for every injured worker. Risk factors to be addressed include: repetitive work, lifting, and forces that have an impact on the lower extremity. In some cases, this requires a jobsite evaluation. There is no single factor or combination of factors that is proven to prevent or ameliorate lower extremity pain, but a combination of ergonomic and psychosocial factors are generally considered to be important. Physical factors that may be considered include use of force, repetitive work, squatting, climbing, kneeling, crouching, crawling, prolonged standing, walking a distance or on uneven surfaces, jumping, running, awkward positions requiring use of force, and lower extremity vibration. Psychosocial factors to be considered include pacing, degree of control over job duties, perception of job stress, and supervisory support.

The job analysis and modification should include input from the employee, employer, and a medical professional familiar with work place evaluation. An ergonomist may also provide useful information. The injured worker must be present and an employee must be observed performing all job functions in order for the jobsite analysis to be valid. Periodic follow-up is recommended to evaluate effectiveness of the intervention and need for additional ergonomic changes.

Ergonomic Changes

Ergonomic changes may be made to modify the hazards identified. In addition, workers should be counseled to vary tasks throughout the day. When possible, employees performing repetitive tasks should take 15 to 30 second breaks every 10 to 20 minutes, or 5-minute breaks every hour. Mini-breaks should include stretching exercises.

Interventions

Interventions should consider engineering controls (e.g., mechanizing the task, changing the tool used, or adjusting the jobsite), or administrative controls (e.g., adjusting the time an individual performs the task).

Medications and Medical Management

Use of medications will vary widely due to the spectrum of injuries from simple strains to complicated fractures. A thorough medication history, including use of alternative and over-the-counter medications, should be performed at the time of the initial visit and updated periodically. Treatment for pain control is initially accomplished with acetaminophen and/or NSAIDs. The patient should be educated regarding the interaction with prescription and over-the-counter medications as well as the contents of over-the-counter herbal products.

NSAIDs and acetaminophen are useful in the treatment of injuries associated with degenerative joint disease and/or inflammation. These same medications can be used for pain control.

Topical agents can be beneficial for pain management in lower extremity injuries. This includes topical capsaicin, non-steroidals, as well as topical iontophoretics/phonophoretics, such as steroid creams and lidocaine.

Glucosamine and chondroitin are sold in the United States as dietary supplements. Their dosage, manufacture, and purity are not regulated by the FDA. There is good evidence that glucosamine sulfate and glucosamine hydrochloride are ineffective for relieving pain in patients with knee or hip OA. There is some evidence that glucosamine sulfate treatment for more than 6 months shows a small improvement in joint function compared to placebo controls in people with osteoarthritis of the knee or hip. There is some evidence that chondroitin plus glucosamine has no clinically important effect on knee pain and function when taken for two years. An effect of slowing of the progression of joint space narrowing cannot be ruled out. However, due to investigations finding that 79% of herbal supplements did not actually contain the substance on the label, these supplements are *not recommended*.

S-adenosyl methionine (SAM-e), like glucosamine and chondroitin, is sold as a dietary supplement in the United States, with a similar lack of standard preparations of dose and manufacture. There is some evidence that a pharmaceutical-grade SAM-e is as effective as celecoxib in improving pain and function in knee osteoarthritis, but its onset of action is slower. Studies using liquid chromatography have shown that it may lose its potency after several weeks of storage. In addition, SAM-e has multiple additional systemic effects. It is *not currently recommended* due to lack of availability of pharmaceutical quality, systemic effects, and loss of potency with storage.

There is insufficient evidence to evaluate if topical herbal therapies (arnica, capsicum, and comfrey extract gels) are effective for treating patients with knee or hip OA. There is insufficient evidence to evaluate if avocado-soybean unsaponifiables (ASU) or the proprietary ASU product Piasclidine® are effective for treating patients with knee or hip OA. There is good evidence that *Boswellia serrata* is marginally effective for decreasing pain and improving function in treating patients with knee or hip OA. However, due to investigations finding that 79% of herbal supplements did not actually contain the substance on the label, these supplements are *not recommended*.

The following are listed in alphabetical order. Refer to the original guideline document for optimum and maximum duration of therapy for each medication.

Acetaminophen

Acetaminophen is an effective analgesic with anti-pyretic but not anti-inflammatory activity. Acetaminophen is generally well tolerated, causes little or no gastrointestinal (GI) irritation and is not associated with ulcer formation. Acetaminophen has been associated with liver toxicity in overdose situations or in chronic alcohol use. Patients may not realize that many over-the-counter preparations may contain acetaminophen. The total daily dose of acetaminophen is recommended not to exceed 3 grams per 24-hour period, from all sources, including narcotic-acetaminophen combination preparations. There is good evidence that acetaminophen is not more effective than placebo for the treatment of knee osteoarthritis. It is likely the acetaminophen is also not effective for hip arthritis either. It may be used on patients with contraindications to other medications.

Bisphosphonates

Bisphosphonates may be used for patients who qualify under osteoporosis guidelines. Long-term use for the purpose of increasing prosthetic fixation is *not recommended* as long-term improvement in fixation is not expected. There is some evidence that a post-surgery single infusion of

zoledronic acid is not effective in reducing the time to clinical osteotomy healing compared to a control infusion. Other medications such as alendronate have been tried for femoral osteonecrosis; however, results are inconsistent. Therefore, they are *not recommended* for those without osteopenia or osteoporosis. See the "Osteoporosis Management" section below.

Deep Venous Thrombosis (DVT) Prophylaxis

DVT prophylaxis is a complex issue involving many variables such as individual patient characteristics, the type of surgery, anesthesia used, and agent(s) used for prophylaxis. Final decisions regarding prophylaxis will depend on the surgeon's clinical judgment.

The following are provided as generally accepted concepts regarding prophylaxis at the time of writing of these guidelines.

All patients undergoing lower extremity surgery or prolonged lower extremity immobilization should be evaluated for elevated risk for DVT and should receive education on prevention. Possible symptoms should be discussed. Patients at higher risk than the normal population include, but are not limited to, those with known hypercoagulable states and those with previous pulmonary embolism or DVT. Those with a higher risk for bleeding may alter thromboprophylaxis protocols. This includes patients with a history of a bleeding disorder, severe renal failure, use of an antiplatelet agent, active liver disease, revision surgery, extensive dissection or difficult to control bleeding. No prophylaxis is recommended for knee arthroscopy in patients without a history of prior venous thrombosis.

Refer to the original guideline document for further discussion of generally accepted concepts regarding DVT prophylaxis.

Doxycycline

There is good evidence that oral doxycycline has no therapeutic effect on knee OA.

Minor Tranquilizer/Muscle Relaxants

Minor tranquilizers/muscle relaxants are appropriate for objective findings of muscle spasm with pain. When prescribing these agents, physicians must seriously consider all central nervous system (CNS) side effects including drowsiness or dizziness and the fact that benzodiazepines may be habit-forming. Carisoprodol should not be used as its active metabolite, meprobamate, is commonly abused. Chronic use of benzodiazepines or any muscle relaxant is *not recommended* due to their habit-forming potential, seizure risk following abrupt withdrawal, and documented contribution to deaths of patients on opioids due to respiratory depression.

NSAIDs

NSAIDs are useful for pain and inflammation. In mild cases, they may be the only drugs required for analgesia. There are several classes of NSAIDs. The response of the individual injured worker to a specific medication is unpredictable. For this reason, a range of NSAIDs may be tried in each case with the most effective preparation being continued. Patients should be closely monitored for adverse reactions. The FDA advises that many NSAIDs may cause an increased risk of serious cardiovascular thrombotic events, myocardial infarction, and stroke, which can be fatal. There is good evidence that naproxen has the least risk for cardiovascular events when compared to other NSAIDs. Administration of proton pump inhibitors, histamine 2 blockers, or prostaglandin analog misoprostol along with these NSAIDs may reduce the risk of duodenal and gastric ulceration in patients at higher risk for this adverse event (e.g., age >60, concurrent antiplatelet or corticosteroid therapy). They do not impact possible cardiovascular complications. Due to the cross-reactivity between aspirin and NSAIDs, NSAIDs should not be used in aspirin-sensitive patients, and should be used with caution in all asthma patients. NSAIDs are associated with abnormal renal function, including renal failure, as well as, abnormal liver function. Patients with renal or hepatic disease may need increased dosing intervals with chronic use. Chronic use of NSAIDs is *generally not recommended* due to increased risk of cardiovascular events and GI bleeding. Topical NSAIDs may be more appropriate for some patients as there is some evidence that topical NSAIDs are associated with fewer systemic adverse events than oral NSAIDs.

Oral and topical NSAIDs are likely to be beneficial in the short-term treatment of acute ankle sprains, but there is no evidence on long-term effects, and oral NSAIDs may be associated with possible adverse events. There is some evidence that a 6 week postoperative course of 75 mg of daily indomethacin does not reduce the risk of heterotopic ossification compared to placebo, and that the risk of nonunion may be increased with 6 weeks of indomethacin. There is some evidence that, in the setting of long bone fractures of the femur, tibia, and humerus, NSAID administration in the first 48 hours after injury is associated with poor healing of the fracture.

Certain NSAIDs may have interactions with various other medications. Individuals may have adverse events not listed above. Intervals for metabolic screening are dependent on the patient's age and general health status and should be within parameters listed for each specific medication. Complete blood count (CBC) and liver and renal function should be monitored at least every 6 months in patients on chronic NSAIDs and initially when indicated.

Refer to the original guideline document for additional information on non-selective NSAIDs and selective cyclo-oxygenase-2 (COX-2) inhibitors.

Opioids

Opioids should be primarily reserved for the treatment of severe lower extremity pain. There are circumstances where prolonged use of opioids is justified based upon specific diagnosis, and in pre- and postoperative patients. In these and other cases, it should be documented and justified. In mild-to-moderate cases of lower extremity pain, opioid medication should be used cautiously on a case-by-case basis. Adverse effects include respiratory depression, the development of physical and psychological dependence, and impaired alertness.

Opioid medications should be prescribed with strict time, quantity, and duration guidelines, and with definitive cessation parameters. Pain is subjective in nature and should be evaluated using a pain scale and assessment of function to rate effectiveness of the opioid prescribed. Any use beyond the maximum should be documented and justified based on the diagnosis and/or invasive procedures.

Oral Steroids

Oral steroids have limited use but are accepted in cases requiring potent anti-inflammatory drug effect in carefully selected patients. A one-week regimen of steroids may be considered in the treatment of patients who have arthritic flare-ups with significant inflammation of the joint. The physician must be fully aware of potential contraindications for the use of all steroids such as hypertension, diabetes, glaucoma, peptic ulcer disease, etc., which should be discussed with the patient.

Osteoporosis Management

Medications/Vitamins: All patients with conditions which require bone healing, especially those over 50, should be encouraged to ingest at least 1000 mg of calcium and 1000 IU of vitamin D per day which is similar to recommendations for older patients or those with osteoporosis and age greater than 50.

Monitoring of vitamin D levels can be considered and may be appropriate for delayed healing of fracture, lack of radiographic signs of healing, or suspected vitamin D deficiency. For all fractures, an initial vitamin D level should be obtained if there is any clinical suspicion of deficiency. Monitoring and treatment for any deficiency should continue as clinically indicated.

There is some evidence that, for women in the older age group (58 to 88) with low hip bone density, greater callus forms for those who adhere to these recommendations than those who do not. Although the clinical implications of this are not known, there is greater non-union in this age group and thus, coverage for these medications during the fracture healing time period is recommended. At this time there is no evidence that bisphosphonates increase acute fracture healing.

Patients with a low energy fracture, female patients 65 and older, and men 70 and older should have a bone mineral density test. A bone mineral density test may also be considered for men and women aged 50 to 69. Patients who have been on prednisone at a dose of 5 mg for more than 3 months should be evaluated for glucocorticoid induced osteoporosis. Risk factors for osteoporosis include alcohol use of 3 or more drinks per day, tobacco use, low body mass index (BMI), parental history of hip fracture, 2^o osteoporosis, age, and rheumatoid arthritis. Those with risk factors for secondary osteoporosis may require further workup.

Patients should be counseled regarding prevention, including decreased alcohol consumption, smoking cessation, regular exercise, and vitamin D and calcium consumption, preferably from dietary sources.

Psychotropic/Anti-anxiety/Hypnotic Agents

Psychotropic/anti-anxiety/hypnotic agents may be useful for treatment of mild and chronic pain, dysesthesias, sleep disorders, and depression.

Antidepressant medications, such as tricyclics and selective serotonin reuptake inhibitors (SSRIs), are useful for affective disorder and chronic pain management. Tricyclic antidepressant agents, in low dose, are useful for chronic neurogenic pain with difficulty sleeping but have more frequent side effects.

There is good evidence that duloxetine more effectively decreases knee OA pain in older adults than placebo. However, the side effect profile of constipation and other symptoms should be considered if the drug is given to older adults.

Anti-anxiety medications are best used for short-term treatment (i.e., less than 6 months). Accompanying sleep disorders are best treated with sedating antidepressants prior to bedtime. Frequently, combinations of the above agents are useful. The physician should be aware of potential drug interactions with these combinations. As a general rule, physicians should assess the patient's prior history of substance abuse or depression prior to prescribing any of these agents.

Due to the habit-forming potential of the benzodiazepines and other drugs found in this class, they are *not generally recommended*. Refer to the Colorado Division of Workers' Compensation [Chronic pain disorder medical treatment guidelines](#) [redacted], which gives a detailed

discussion regarding medication use in chronic pain management.

Topical Drug Delivery

Creams and patches may be an alternative treatment of localized musculoskeletal disorders. It is necessary that all topical agents be used with strict instructions for application as well as the maximum number of applications per day to obtain the desired benefit and avoid potential toxicity. As with all medications, patient selection must be rigorous to select those patients with the highest probability of compliance. Refer to the "Iontophoresis" section in the original guideline for information regarding topical iontophoretic agents. Also refer to the original guideline for additional information on topical salicylates and non-salicylates and topical capsaicin.

Tramadol

Tramadol was recently classified as a controlled substance in the U.S. Tramadol is useful in relief of pain and has been shown to provide pain relief equivalent to that of commonly prescribed NSAIDs. Tramadol is an atypical opioid with norepinephrine and serotonin reuptake inhibition. Although Tramadol may cause impaired alertness, it is generally well tolerated, does not cause GI ulceration and does not exacerbate hypertension or congestive heart failure. Tramadol should be used cautiously in patients who have a history of seizures or who are taking medication that may lower the seizure threshold, such as monoamine oxidase (MAO) inhibitors, SSRIs, some muscle relaxants, and tricyclic antidepressants. This medication has physically addictive properties, and withdrawal may follow abrupt discontinuation; thus, it is *not recommended* for patients with prior opioid addiction. Careful dose titration is recommended as some patients experience intolerance.

Tranexamic Acid

Tranexamic acid is an effective antifibrinolytic agent which decreases the need for blood transfusions. It is usually given in two doses intravenously or topically on the surgical site. There is strong evidence that tranexamic acid in the setting of total knee arthroplasty reduces blood loss, reduces the risk of transfusion, and reduces the number of units transfused, without increasing the risk of pulmonary embolus or deep vein thrombosis. It is also used for hip arthroplasty. Contraindications include patients with hypercoagulable states, cardiac stents, previous strokes. Dosage should be adjusted for those with renal compromises.

Occupational Rehabilitation Programs

Non-Interdisciplinary

These generally accepted programs are work-related, outcome-focused, individualized treatment programs. Objectives of the program include, but are not limited to, improvement of cardiopulmonary and neuromusculoskeletal functions (strength, endurance, movement, flexibility, stability, and motor control functions), patient education, and symptom relief. The goal is for patients to gain full or optimal function and return to work. The service may include the time-limited use of passive modalities with progression to achieve treatment and/or simulated/real work. Refer to the original guideline document for length of visit, frequency, and optimum and maximum duration for each program.

Work Conditioning

These programs are usually initiated once reconditioning has been completed but may be offered at any time throughout the recovery phase. It should be initiated when imminent return of a patient to modified or full duty is not an option, but the prognosis for returning the patient to work at completion of the program is at least fair to good.

Work Simulation

Work simulation is a program where an individual completes specific work-related tasks for a particular job and return to work. Use of this program is appropriate when modified duty can only be partially accommodated in the work place, when modified duty in the work place is unavailable, or when the patient requires more structured supervision. The need for work place simulation should be based upon the results of a functional capacity evaluation and/or jobsite analysis.

Orthotics and Prosthetics

Refer to the original guideline document for time to produce effect, frequency and optimum/maximum duration for each of the interventions described below.

Fabrication/Modification of Orthotics

These would be used when there is need to normalize weight-bearing, facilitate better motion response, stabilize a joint with insufficient muscle or proprioceptive/reflex competencies, to protect subacute conditions as needed during movement, and correct biomechanical problems. Footwear modifications may be necessary for work shoes and everyday shoes. Replacement is needed every 6 months to one year. For specific types of

orthotics/prosthetics see Section E, "Specific Lower Extremity Injury Diagnosis, Testing and Treatment" in the original guideline document.

Orthotic/Prosthetic Training

Orthotic/prosthetic training is the skilled instruction (by qualified providers) in the proper use of orthotic devices and/or prosthetic limbs including stump preparation, donning and doffing limbs, instruction in wearing schedule and orthotic/prosthetic maintenance training. Training can include gait, mobility, transfer and self-care techniques.

Splints or Adaptive Equipment

Indications for splints and adaptive equipment include the need to 1) control stress during functional activities following neurological and orthopedic injuries and 2) modify tasks through instruction in the use of a device or physical modification of a device. This includes design, fabrication, and/or modification. Equipment and any associated training should improve safety and reduce risk of re-injury. This includes high and low technology assistive options such as workplace modifications, crutch or walker training, and self-care aids. Night splinting is commonly used for plantar fasciitis and may be incorporated as a part of the stretching protocol.

Personality/ Psychosocial/ Psychological Intervention

Psychosocial treatment is a well-established therapeutic and diagnostic intervention with selected use in acute pain problems and more widespread use in sub-acute and chronic pain populations. Psychosocial treatment is recommended as an important component in the total management of a patient with chronic pain and should be implemented as soon as the problem is identified. If a diagnosis consistent with the standards of the American Psychiatric Association's Diagnostic and Statistical Manual of Mental Disorders (DSM) has been determined, the patient should be evaluated for the potential need for psychiatric medications.

Use of any medication to treat a diagnosed condition may be ordered by the authorized treating physician or by the consulting psychiatrist. Visits for management of psychiatric medications are medical in nature and are not a component of psychosocial treatment. Therefore, separate visits for medication management may be necessary, depending on the patient and medications selected.

Psychosocial interventions include psychotherapeutic treatments for mental health conditions, as well as behavioral medicine treatments. These interventions may similarly be beneficial for patients without psychiatric conditions, but who may need to make major life changes in order to cope with pain or adjust to disability. Examples of these treatments include cognitive behavioral therapy (CBT), relaxation training, mindfulness training, and sleep hygiene training. The screening or diagnostic workup should clarify and distinguish between pre-existing, aggravated, and/or purely causative psychological conditions.

Therapeutic and diagnostic modalities include, but are not limited to, individual counseling and group therapy. Treatment can occur within an individualized model, a multi-disciplinary model, or a structured pain management program.

CBT refers to a group of psychological therapies that are sometimes referred to by more specific names such as Rational Emotive Behavior Therapy, Rational Behavior Therapy, Rational Living Therapy, Cognitive Therapy, and Dialectic Behavior Therapy. Variations of CBT methods can be used to treat a variety of conditions, including chronic pain, depression, anxiety, phobias, and post-traumatic stress disorder (PTSD). For patients with multiple diagnoses, more than one type of CBT might be needed.

Refer to the original guideline document for additional information on CBT and other similar treatment, including time to produce effect, frequency, and optimum/maximum duration of therapy.

Restriction of Activities

Continuation of normal daily activities is the recommendation for most patients since immobility will negatively affect rehabilitation. Some level of immobility may occasionally be appropriate which could include bracing. While these interventions may occasionally have been ordered in the acute phase, the provider should be aware of their impact on the patient's ability to adequately comply with and successfully complete rehabilitation. Activity should be increased based on the improvement of core strengthening. Patients should be educated regarding the detrimental effects of immobility versus the efficacious use of limited rest periods. Adequate rest allows the patient to comply with active treatment and benefit from the rehabilitation program. In addition, complete work cessation should be avoided, if possible, since it often further aggravates the pain presentation and promotes disability. Modified return to work is almost always more efficacious and rarely contraindicated in the vast majority of injured workers.

Return to Work

Return to work and/or work-related activities whenever possible is one of the major components in treatment and rehabilitation. Return to work is a subject that should be addressed by each workers' compensation provider at the first meeting with the injured employee and updated at each

additional visit. A return-to-work format should be part of a company's health plan, knowing that return to work can decrease anxiety, reduce the possibility of depression, and reconnect the worker with society. Because a prolonged period of time off work will decrease the likelihood of return to work, the first weeks of treatment are crucial in preventing and/or reversing chronicity and disability mindset. In complex cases, experienced nurse case managers may be required to assist in return to work. Other services, including psychological evaluation and/or treatment, jobsite analysis, and vocational assistance, may be employed. Two counseling sessions with an occupational physician, and work site visit if necessary, may be helpful for workers who are concerned about returning to work.

The following should be considered when attempting to return an injured worker with chronic pain to work:

- Job history interview
- Coordination of care
- Communication
- Establishment of return-to-work status
- Establishment of activity level restrictions
- Rehabilitation and return to work
- Vocational assistance

Refer to the original guideline document for detailed information on the procedures listed above.

Recommendations to Employers and Employees of Small Businesses

Employees of small businesses who are diagnosed with chronic pain may not be able to perform any jobs for which openings exist. Temporary employees may fill those slots while the employee functionally improves. Some small businesses hire other workers, and if the injured employee returns to the job, the supervisor/owner may have an extra employee. Case managers may assist with resolution of these problems, as well as assist in finding modified job tasks, or find jobs with reduced hours, etc., depending on company philosophy and employee needs.

Recommendations to Employers and Employees of Mid-sized and Large Businesses

Employers are encouraged by the Division to identify modified work within the company that may be available to injured workers with chronic pain who are returning to work with temporary or permanent restrictions. To assist with temporary or permanent placement of the injured worker, it is suggested that a program be implemented that allows the case manager to access descriptions of all jobs within the organization.

Therapy—Active

The following active therapies are widely used and accepted methods of care for a variety of work-related injuries. They are based on the philosophy that therapeutic exercise and/or activity are beneficial for restoring flexibility, strength, endurance, function, range-of-motion, and can alleviate discomfort. Active therapy requires individual effort to complete a specific exercise or task. This form of therapy requires supervision from a therapist or medical provider such as verbal, visual and/or tactile instruction(s). At times, the provider may help stabilize the patient or guide the movement pattern but the energy required to complete the task predominately comes from the patient.

Patients should be instructed to continue active therapies at home as an extension of the treatment process in order to maintain improvement levels. Follow-up visits to reinforce and monitor progress and proper technique are recommended. Home exercise can include exercise with or without mechanical assistance or resistance and functional activities with assistive devices.

On occasion, specific diagnoses and post-surgical conditions may warrant durations of treatment beyond those listed as "maximum." Factors such as exacerbation of symptoms, re-injury, interrupted continuity of care, and co-morbidities may also extend durations of care. Specific goals with objectively measured functional improvement during treatment must be cited to justify extended durations of care. It is recommended that, if no functional gain is observed after the number of treatments under "time to produce effect" have been completed, then alternative treatment interventions, further diagnostic studies, or further consultations should be pursued.

The following active therapies are listed in alphabetical order. Refer to the original guideline document for a description of the following active therapies including time to produce effect, frequency, and optimum and maximum duration of treatment:

- Activities of daily living (ADL)
- Aquatic therapy
- Functional activities
- Functional electrical stimulation
- Gait training
- Neuromuscular re-education

- Therapeutic exercise
- Wheelchair management and propulsion

Therapy—Passive

Most of the following passive therapies and modalities are generally well-accepted methods of care for a variety of work-related injuries. Passive therapy includes those treatment modalities that do not require energy expenditure on the part of the patient. They are principally effective during the early phases of treatment and are directed at controlling symptoms such as pain, inflammation and swelling, as well as improving the rate of healing soft tissue injuries. They should be used adjunctively with active therapies to help control swelling, pain, and inflammation during the rehabilitation process. They may be used intermittently as a therapist deems appropriate or regularly if there are specific goals with objectively measured functional improvements during treatment.

On occasion, specific diagnoses and post-surgical conditions may warrant durations of treatment beyond those listed as "maximum." Factors such as exacerbation of symptoms, re-injury, interrupted continuity of care and comorbidities may also extend durations of care. Specific goals with objectively measured functional improvement during treatment must be cited to justify extended durations of care. It is recommended that, if no functional gain is observed after the number of treatments under "time to produce effect" has been completed alternative treatment interventions, further diagnostic studies, or further consultations should be pursued.

The following passive therapies and modalities are listed in alphabetical order. Refer to the original guideline document for a description of the following passive therapies including time to produce effect, frequency, and optimum and maximum duration of treatment:

- Continuous passive motion (CPM) (*generally not recommended*)
- Contrast baths
- Dynamic splinting
- Electrical stimulation (unattended)
- Fluidotherapy
- Hyperbaric oxygen therapy (*not recommended*)
- Infrared therapy
- Iontophoresis
- Manipulation
- Manual electrical stimulation
- Massage—manual or mechanical
- Mobilization (joint)
- Mobilization (soft tissue)
- Paraffin bath
- Superficial heat and cold therapy
- Short-wave diathermy
- Traction
- Transcutaneous electrical nerve stimulation (TENS)
- Ultrasound
- Vasopneumatic devices

Vocational Rehabilitation

Vocational rehabilitation is a generally accepted intervention, but Colorado law limits its use. Initiation of vocational rehabilitation requires adequate evaluation of patients for quantification of highest functional level, motivation and achievement of maximum medical improvement (MMI). Vocational rehabilitation may be as simple as returning to the original job or as complicated as being retrained for a new occupation. The effectiveness of vocational rehabilitation may be enhanced when performed in combination with work hardening or work conditioning.

It may also be beneficial for full vocational rehabilitation to be started before MMI if it is evident that the injured worker will be unable to return to his/her previous occupation. A positive goal and direction may aid the patient in decreasing stress and depression, and promote optimum rehabilitation.

Therapeutic Procedures—Operative

All operative interventions must be based upon positive correlation of clinical findings, clinical course and diagnostic tests. A comprehensive assimilation of these factors must lead to a specific diagnosis with positive identification of pathologic condition(s). It is imperative to rule out non-physiologic modifiers of pain presentation or non-operative conditions mimicking operative conditions (e.g., peripheral neuropathy, myofascial

pain, scleratogenous or sympathetically mediated pain syndromes, psychological conditions) prior to consideration of elective surgical intervention.

In addition, operative treatment is indicated when the natural history of surgically treated lesions is better than the natural history for non-operatively treated lesions. All patients being considered for surgical intervention should first undergo a comprehensive neuromusculoskeletal examination to identify mechanical pain generators that may respond to non-surgical techniques or may be refractory to surgical intervention.

Structured rehabilitation interventions should strongly be considered postoperatively in any patient not making expected functional progress within three weeks after surgery. Postoperative therapy will frequently require a repeat of the therapy provided pre-operatively.

Refer to "Therapeutic Procedures—Non-operative" section, and consider the first postoperative visit as visit number one, for the time frame parameters provided. Return-to-work restrictions should be specific according to the recommendation in "Return to work" section.

The patient and treating physician should have identified functional operative goals and the likelihood of achieving improved ability to perform activities of daily living or work. The patient should agree to comply with the pre- and postoperative treatment plan, including home exercise. The provider should be especially careful to make sure the patient understands the amount of postoperative treatment required and the length of partial and full disability expected postoperatively. The patient should have committed to the recommended postoperative treatment plan and fully completed the recommended active, manual and pre-operative treatment plans. Informed decision making should be documented for all invasive procedures. This must include a thorough discussion of the pros and cons of the procedure and the possible complications as well as the natural history of the identified diagnosis.

Refer to the original guideline document for additional information on surgical indications/considerations, operative procedures, and postoperative treatment for each of the following procedures.

Ankle and Subtalar Fusion

- a. Description/Definition: Surgical fusion of the ankle or subtalar joint.
- b. Occupational Relationship: Usually post-traumatic arthritis or residual deformity.
- c. Specific Physical Exam Findings: Painful, limited range of motion of the joint(s). Possible fixed deformity.
- d. Diagnostic Testing Procedures: Radiographs. Diagnostic injections, magnetic resonance imaging (MRI), computed tomography (CT) scan, and/or bone scan.

Knee Fusion

- a. Description/Definition: Surgical fusion of femur to the tibia at the knee joint.
- b. Occupational Relationship: Usually from post-traumatic arthritis or deformity.
- c. Specific Physical Exam Findings: Stiff, painful, sometime deformed limb at the knee joint.
- d. Diagnostic Testing Procedures: Radiographs, MRI, CT, diagnostic injections or bone scan.

Ankle Arthroplasty

- a. Description/Definition: Prosthetic replacement of the articulating surfaces of the ankle joint.
- b. Occupational Relationship: Usually from post-traumatic arthritis.
- c. Specific Physical Exam Findings: Stiff, painful ankle. Limited range-of-motion of the ankle joint.
- d. Diagnostic Testing Procedures: Radiographs, MRI, diagnostic injections, CT scan, bone scan.

Knee Arthroplasty

- a. Description/Definition: Prosthetic replacement of the articulating surfaces of the knee joint.
- b. Occupational Relationship: Usually from post-traumatic osteoarthritis.
- c. Specific Physical Exam Findings: Stiff, painful knee, and possible effusion.
- d. Diagnostic Testing Procedures: Radiographs.

Hip Arthroplasty

- a. Description/Definition: Prosthetic replacement of the articulating surfaces of the hip joint. In some cases, hip resurfacing may be performed.
- b. Occupational Relationship: Usually from post-traumatic arthritis, hip dislocations and femur or acetabular fractures. Patients with intracapsular femoral fractures have a risk of developing avascular necrosis of the femoral head requiring treatment months to years after the initial injury.
- c. Specific Physical Exam Findings: Stiff, painful hip.

- d. Diagnostic Testing Procedures: Standing pelvic radiographs demonstrating joint space narrowing to 2 mm or less, osteophytes or sclerosis at the joint. MRI may be ordered to rule out other more serious disease.

Amputation

- a. Description/Definition: Surgical removal of a portion of the lower extremity.
- b. Occupational Relationship: Usually secondary to post-traumatic bone, soft tissue, vascular or neurologic compromise of part of the extremity.
- c. Specific Physical Exam Findings: Non-useful or non-viable portion of the lower extremity.
- d. Diagnostic Testing Procedures: Radiographs, vascular studies, MRI, bone scan.

Manipulation Under Anesthesia

- a. Description/Definition: Passive range of motion of a joint under anesthesia.
- b. Occupational Relationship: Joint stiffness that usually results from a traumatic injury, compensation related surgery, or other treatment.
- c. Specific Physical Exam Findings: Joint stiffness in both active and passive modes.
- d. Diagnostic Testing Procedures: Radiographs, CT, MRI, diagnostic injections.

Osteotomy

- a. Description/Definition: A reconstructive procedure involving the surgical cutting of bone for realignment. It is useful for patients that would benefit from realignment in lieu of total joint replacement.
- b. Occupational Relationship: Post-traumatic arthritis or deformity.
- c. Specific Physical Exam Findings: Painful decreased range of motion and/or deformity.
- d. Diagnostic Testing Procedures: Radiographs, MRI scan, CT scan.

Hardware Removal

Hardware removal frequently occurs after initial MMI. Physicians should document the possible need for hardware removal and include this as treatment in their final report on the WC 164 form.

- a. Description/Definition: Surgical removal of internal or external fixation device, commonly related to fracture repairs.
- b. Occupational Relationship: Usually following healing of a post-traumatic injury that required fixation or reconstruction using instrumentation.
- c. Specific Physical Exam Findings: Local pain to palpation, swelling, erythema.
- d. Diagnostic Testing Procedures: Radiographs, tomography, CT scan, MRI.

Release of Contracture

- a. Description/Definition: Surgical incision or lengthening of contracted tendon or peri-articular soft tissue.
- b. Occupational Relationship: Usually following a post-traumatic complication.
- c. Specific Physical Exam Findings: Shortened tendon or stiff joint.
- d. Diagnostic Testing Procedures: Radiographs, CT scan, MRI scan.

Human Bone Morphogenetic Protein (RHBMP)

Bone morphogenetic proteins (BMPs) are proteins secreted by cells which serve as signaling agents that influence cell division, matrix synthesis, and tissue differentiation. Most BMP studies examine utility in tibial fractures. For acute tibial fractures, BMP has been used at the site of fracture in conjunction with reamed or underreamed intramedullary nail fixation in an effort to promote bone formation and fracture healing. It has also been used in tibial nonunion.

There is currently a lack of evidence to recommend the use of BMP in the treatment of tibial fractures. There is good evidence that there are no measureable benefits of BMP over standard of care without BMP for tibial fractures. There is good evidence that, for open tibial shaft fractures, BMP does not enhance fracture healing at 20 weeks compared to fracture fixation with intramedullary nailing. Addition of BMP does not accelerate healing in the treatment of acute open tibial fractures, result in significant gains in attaining union without a secondary procedure over the standard of care, or affect the risk of hardware failure. If unusual circumstances arise, a provider may feel that a patient will benefit from addition of BMP. BMP should only be used for long bone fractures with a nonunion or high risk arthrodesis procedures and requires prior authorization.

Clinical Algorithm(s)

None provided

Scope

Disease/Condition(s)

Lower extremity injuries:

- Foot and ankle injuries
- Knee injuries
- Hip and leg injuries

Guideline Category

Counseling

Management

Rehabilitation

Treatment

Clinical Specialty

Chiropractic

Family Practice

Internal Medicine

Orthopedic Surgery

Physical Medicine and Rehabilitation

Podiatry

Psychiatry

Psychology

Radiology

Rheumatology

Surgery

Intended Users

Advanced Practice Nurses

Chiropractors

Health Care Providers

Health Plans

Hospitals

Managed Care Organizations

Nurses

Occupational Therapists

Patients

Physical Therapists

Physician Assistants

Physicians

Podiatrists

Psychologists/Non-physician Behavioral Health Clinicians

Social Workers

Utilization Management

Guideline Objective(s)

To provide advisory and educational guidelines for the treatment of a lower extremity injury that are enforceable under the Colorado Workers' Compensation Rules of Procedure

Target Population

Individuals qualifying under Colorado's Workers' Compensation Act as injured workers with a lower extremity injury

Interventions and Practices Considered

Non-operative Therapeutic Procedures*

1. Acupuncture (including acupuncture with electrical stimulation and other modalities)
2. Biofeedback
3. Bone-growth stimulators
 - Electrical
 - Low-intensity pulsed ultrasound (LIPUS)
4. Education/informed decision making
5. Extracorporeal shock wave therapy (ESWT)
6. Therapeutic injections
 - Steroid injections
 - Soft tissue injections
 - Stem cell injections
 - Platelet-rich plasma (PRP)
 - Viscosupplementation/intracapsular acid salts
 - Prolotherapy
 - Trigger point injections and dry needling
 - Botulinum toxin injections
7. Interdisciplinary rehabilitation programs (formal and informal)
8. Jobsite alteration
9. Medications and medical management
 - Acetaminophen
 - Bisphosphonates
 - Deep venous thrombosis prophylaxis

- Doxycycline
 - Minor tranquilizer/muscle relaxants
 - Non-steroidal anti-inflammatory drugs (NSAIDs)
 - Opioids
 - Oral steroids
 - Osteoporosis management
 - Psychotropic/anti-anxiety/hypnotic agents
 - Topical drug delivery
 - Tramadol
 - Tranexamic acid
10. Occupational rehabilitation programs (non-interdisciplinary)
 11. Orthotics and prosthetics
 12. Patient education
 13. Personality/psychological/psychosocial interventions (cognitive behavioral therapy [CBT] and similar treatment)
 14. Restriction of activities
 15. Return-to-work
 16. Active therapy
 - Activities of daily living (ADL)
 - Aquatic therapy
 - Functional activities
 - Functional electrical stimulation
 - Gait training
 - Neuromuscular re-education
 - Therapeutic exercise
 - Wheelchair management and propulsion
 17. Passive therapy
 - Continuous passive motion (CPM)
 - Contrast baths
 - Dynamic splinting
 - Electrical stimulation (unattended)
 - Fluidotherapy
 - Hyperbaric oxygen therapy
 - Infrared therapy
 - Iontophoresis
 - Manipulation
 - Manual electrical stimulation
 - Massage – manual or mechanical
 - Mobilization (joint)
 - Mobilization (soft tissue)
 - Paraffin bath
 - Superficial heat and cold therapy
 - Short-wave diathermy
 - Traction
 - Transcutaneous electrical nerve stimulation (TENS)
 - Ultrasound
 - Vasopneumatic devices
 18. Vocational rehabilitation

Operative Therapeutic Procedures*

1. Ankle and subtalar fusion
2. Knee fusion
3. Ankle arthroplasty
4. Knee arthroplasty
5. Hip arthroplasty

6. Amputation
7. Manipulation under anesthesia
8. Osteotomy
9. Hardware removal
10. Release of contracture
11. Human bone morphogenetic protein (RhBMP)

*Note: Not all of the listed interventions and practices are recommended routinely or generally. See the "Major Recommendations" field and the original guideline document.

Major Outcomes Considered

- Functional improvement (time to return to work, ability to return to original job, etc.)
- Change in pain scores
- Duration of therapeutic effect
- Time on disability
- Side effects or complications
- Rate of secondary surgery
- Activities of daily living and quality of life

Methodology

Methods Used to Collect/Select the Evidence

Hand-searches of Published Literature (Primary Sources)

Hand-searches of Published Literature (Secondary Sources)

Searches of Electronic Databases

Description of Methods Used to Collect/Select the Evidence

General Literature Search Strategy for Medical Treatment Guidelines

Studies were identified through the electronic database of PubMed (with specified search topics), and related links from articles identified by searches. For some articles, Web of Science, a literature citation database, was used when it was desirable to find literature that cited a particular article. Relevant evidence statements from Cochrane and British Medical Journal (BMJ) Clinical Evidence were reviewed. Selected guidelines/systematic reviews were also reviewed. The reference lists from other literature and tables of content from related journals were scanned for relevant articles. Suggestions from various volunteer advisory bodies to the Division of Workers' Compensation were solicited.

Literature reviewed was in English. Literature searches were limited according to study type and human adults. Only randomized clinical trials (RCTs) or meta-analyses were used for evidence statements regarding treatment. RCTs that compared an intervention (for example, surgery) with not using that intervention (for example, non-operative treatment) were designated as more relevant to workers' compensation guidelines than those RCTs which compared variations on technique or types of devices.

Beginning with the Traumatic Brain Injury Medical Treatment Guidelines Revision of 2012, if meta-analyses were of high enough quality, then previous RCTs that were incorporated into the selected meta-analyses may not have been individually critiqued. Selected RCTs published after Cochrane meta-analyses were evaluated as to whether they would have likely met the Cochrane inclusion criteria. If so, the Cochrane software (RevMan) was used to update the pooled effect measure and compare it with the original Cochrane report. Diagnostic accuracy studies were critiqued for diagnostic testing evidence and cohort, cross-sectional and case-control studies were critiqued for causation evidence statements. Literature which did not meet requirements for evidence statements could be referenced if it furnished useful background information or described interventions which are considered generally accepted by a consensus of health care providers. This information sometimes contributed to consensus decisions by the multi-disciplinary task force drafting the guidelines. Literature that was determined either be unrelated to the clinical issue, did not reflect interventions likely to occur in Colorado, or which had such poor quality on initial review that it could not qualify for evidence nor provide meaningful input was not critiqued. All articles sent by the public were formally reviewed.

Specific Search Strategy

All searches were done on PubMed. The literature search included articles published from December 2008 to October 2014. The date of the search was October 2014.

Limiting Criteria: Human; Adults; Meta-analysis; Randomized Controlled Trial.

Search Terms: Refer to the "Search Terms - Lower Extremity Injury Medical Treatment Guidelines" companion document (see the "Availability of Companion Documents" field) for the specific search terms used.

Abstracts were reviewed and articles were then excluded based on the criteria below:

- Lack of relevancy to workers' compensation non-chronic back pain population
- Major obvious errors in study protocol (e.g., lack of control group even though study was listed as an RCT).
- Whether they were included in another meta-analysis (e.g., Cochrane Collaboration, BMJ Clinical Evidence).
- Duplicates
- Study too old
- Cadaverous studies
- Pediatric population
- Preliminary results
- Healthy volunteers
- Studies not applicable to treatment guidelines spine conditions, such as tumor studies
- Studies too technical in nature to meet the objective of the guideline (examples, types of screws used in surgery).

Number of Source Documents

Number of articles initially identified: 2,485

Number of articles excluded from those initially identified: 1,797

Number of articles selected for further review: 688

Number of articles used to support evidence statements: 184 ("Strong Evidence" - 21, "Good Evidence" - 85, "Some Evidence" - 78).

Methods Used to Assess the Quality and Strength of the Evidence

Subjective Review

Weighting According to a Rating Scheme (Scheme Given)

Rating Scheme for the Strength of the Evidence

Grading of Systematic Reviews and Meta-Analyses

Criterion	Green	Yellow	Red	Comments
The study is in fact identified as a systematic review or meta-analysis	"Systematic review," "meta-analysis," or both, are in the title of the article, and the abstract supports the design in the title	The title is ambiguous, but the abstract shows that the authors did a systematic review	The article is a narrative review or an overview, or is done by a single author	"Systematic review" and "meta-analysis" are generally recognized terms for a specific type of original research; narrative reviews are subject to biases which systematic reviews and meta-analyses methodically control for
Objectives of the systematic	Clearly stated in terms of PICOS: Patient population (disease, age, setting), Intervention	PICOS elements all reported, but	One or more PICOS element	The question being addressed should be clear

Criterion	Green	Yellow	Red	Comments
review of meta-analysis	(dose, frequency, etc), Comparator (control group interventions), Outcome (morbidity, mortality, symptoms, function), and Study design (randomized trials only, broader design criteria)	some ambiguity in some elements (e.g., Comparator described as "standard care" or "usual care" without further description)	missing or uninterpretable	from the abstract: it may be narrow or broad, but the scope and potential applicability should be well defined
Characteristics of eligible studies	In addition to PICOS, study characteristics defined in terms of restrictions for inclusion (e.g., minimum length of follow-up, whether co-interventions are included), and scope of reports (language, years of publication, unpublished material)	Ambiguity exists for some of the characteristics of eligible studies	Eligibility of studies is unclear, and scope of reports is not specified	
Information sources	Multiple information sources are clearly specified: databases (PubMed, Ovid, EMBASE, Cochrane, Web of Science), hand searches of tables of contents of relevant journals, meeting abstracts, reference lists, contacts with authors, manufacturers, trial registries)	Search limited to published material from two or more sources, without additional searching of registries or contact with authors	Search limited to a single information source (e.g., PubMed only)	While PubMed is a large and nearly comprehensive database, its yield can be influenced by how articles are indexed by the National Library of Medicine; additional sources of information can materially affect the conclusions of a systematic review or meta-analysis
Search strategy	Full electronic search strategy for at least one major database, with dates (e.g., PubMed 1970-October 2009), limits, combinations of search terms, such that it can be replicated by the reader	Databases and search terms are given, but there is some ambiguity in the strategy (e.g., PubMed "through 2007"), and replication by the reader would be difficult	Databases and search terms are too broad and vague to permit replication by the reader	Often given in an appendix to the article or in an online supplement, the strategy should be readily accessible
Study selection	Specification of which criteria determine eligibility for inclusion (e.g., randomization to specified interventions, which outcomes were required to be reported) and for quality (e.g., allocation concealment, intention-to-treat analysis, blinding) with at least two reviewers identified by initials; inter-rater agreement and methods of resolving disagreement are specified; a flow diagram enumerates articles retrieved from search, articles excluded after screening, and articles included for meta-analysis	Two or more reviewers screen articles for inclusion, but there is some ambiguity in the criteria for inclusion or for inter-rater agreement and methods of resolving disagreement; flow diagram is lacking	Only one reviewer selects studies; criteria are vague	Quality assessment should focus on risk of bias; scoring of articles for quality is not necessary and may be misleading. There is no standard process for selecting studies, but the process used by the reviewers should be clear enough to allow the reader to determine which studies might meet the test of inclusion
Outcomes for analysis	Meta-analysis is restricted to pre-specified primary and secondary outcomes, and exploratory (hypothesis-generating) analyses in the source literature are excluded from meta-analysis	Meta-analysis combines pre-specified primary and secondary outcomes in the source literature with exploratory analyses in the same literature, but assigns exploratory analyses a lower weight	Meta-analysis treats exploratory analyses in source literature on an equal basis with the pre-specified primary and secondary analyses	Exploratory analyses are too likely to be reported when they arise from the play of chance, and should not be included in any meta-analysis of the same outcomes; their inclusion is likely to bias the meta-analysis
Summary measures for	Principal summary measures (relative risk, risk difference, odds ratio, difference in means,	Risk ratios or odds ratios are reported,	Risk ratios or odds ratios are	Relative risks and odds ratios are generally more stable for

Criterion	Green	Yellow	Red	Comments
meta-analysis with or without pooled Number Needed to Treat (NNT)	hazard ratio) are specified and appropriate to the outcome measure; if NNT are reported, there is a fixed event rate in the control groups for the studies being combined	and NNT is not reported if there is a difference in the control group event rates across the different studies	reported, but NNT is reported even when there is a difference in control group event rates across the different studies (the underlying baseline risks are not equal)	summary measures than risk differences; pooled NNT is misleading if the control group event rate (the baseline risk) is different across studies, even if the risk ratio is the same
Meta-analysis presentation	Results of meta-analysis are presented as an estimated summary effect (with confidence interval) across all included studies, displaying a forest plot with weights and confidence intervals for the included studies; a measure of heterogeneity is presented (e.g., I^2); the choice of fixed effect or random effects model is explained, and, if there is significant heterogeneity, there is an attempt to examine possible sources of heterogeneity	Estimated summary effect with confidence interval, with an estimate of heterogeneity, and an explanation of the choice of fixed or random effects model; however, an examination of sources of heterogeneity is lacking	Summary effect measure with confidence interval, but heterogeneity measures and examinations are lacking	No hard and fast rule dictates the choice of model, but because a fixed effect model assumes a single common effect size across studies, there should be a discussion of why it is appropriate for the included studies

Methods Used to Analyze the Evidence

Meta-Analysis

Review of Published Meta-Analyses

Systematic Review with Evidence Tables

Description of the Methods Used to Analyze the Evidence

Criteria for evidence are drawn principally from the Cochrane Risk of Bias tool for individual randomized trials and from the PRISMA statement for systematic reviews. Nonrandomized trials may sometimes be upgraded to evidence statements when all Grading of Recommendations Assessment, Development and Evaluation (GRADE) criteria are met.

The strength and limitations of the body of evidence are clearly identified. Division of Workers' Compensation Assessment Criteria on Systematic Reviews and Meta-analyses list assessment criteria for strengths and limitations of selected bodies of literature (see the "Rating Scheme for the Strength of the Evidence" field). Also, areas that do not have evidence and thus are consensus-based are delineated in the guidelines.

The evidence table contains summaries of the critiques that were completed for individual scholarly articles used in the Lower Extremity Injury Medical Treatment Guidelines. Scholarly articles are given an assessment of "adequate," "inadequate," or "high quality." When Division of Workers' Compensation staff completed additional statistical pooling, this is noted in the "Division Staff Assessment Column using RevMan (Cochrane Collaboration of Systematic Reviews). These are denoted with a **. In multiple cases, literature from the Cochrane Collaboration was reviewed.

It should be noted that one scholarly article may be graded at different levels for different interventions. For those deemed inadequate, a brief rationale is provided. The criteria for the aforementioned assessment designations are located on the [Division of Workers' Compensation Web site](#) .

The articles that are graded as either adequate or high quality are then translated into "some evidence," "good evidence," and "strong evidence" as defined in the General Guidelines Principles, located in each of the Division Medical Treatment Guidelines (see the "Rating Scheme for the Strength of the Recommendations" field).

Because the guideline developers synthesize the medical evidence as much as possible, one assessment (or group of assessments) may potentially create more than one evidence statement. It is also possible that two assessments may be combined (e.g., two "adequates" to create a higher level

of evidence (for example, elevating a statement from "some" to "good" evidence).

This evidence table is a summary and based on critiques of scholarly articles. The full critiques are publicly available on the Division of Workers' Compensation Web site (see the "Availability of Companions Documents" field).

Methods Used to Formulate the Recommendations

Expert Consensus

Description of Methods Used to Formulate the Recommendations

Evidence statements are formatted. General clinical reviews are collected and used to make suggested recommendations for consensus consideration. The Task Force reaches consensus by vote (unanimous decision in most cases). The health benefits, side effects and risks are considered in formulating the recommendations. These are fully described for groups and considered by the Task Force. There is an explicit link between recommendations and supporting evidence (presented in the referenced version of the guideline on the Department of Workers' Compensations Web site, wherein each evidence statement is accompanied by author and year of the bibliography/critiqued article).

Guidelines Updating Process

The State of Colorado Division of Workers' Compensation Medical Treatment Guidelines updating process is completed in several stages. Initially, current medical literature related to the guideline is reviewed, critiqued, and graded by the Division and the multi-disciplinary Task Force. Next, appropriate medical evidence and consensus are incorporated concurrently into the Guideline, section by section. During this stage, Task Force members will be appointed for projects, working in sub-groups or individually, according to the task.

Guideline updating processes and resources dedicated to supporting the Task Force include:

- Medical literature review and grading, with the assistance of a professional Research Methodologist and Epidemiologist
- Evidence and consensus parameters to assist in the revision and evaluation of treatment recommendations
- A multi-disciplinary Advisory Panel and other advisory bodies to provide clinical feedback to the Task Force and the Division
- Administrative support and coordination, allowing participants to focus on clinical issues
- Opportunities for members to provide feedback on ways to improve the update process

Selection of Task Force Members

Health care disciplines required to participate in the task force process are identified. Individuals selected should be Level I or II Accredited Providers (if applicable), Board Certified in their area of specialty, in good standing within their medical specialty organization, and specialize in treatment of injured workers. Task force membership also includes non-physician members of the workers' compensation system, such as: therapists, psychologists, attorneys, and risk managers. Prior task force participation is not necessary.

Grading Recommendations

Graded consensus recommendations were developed based on the considered judgment of the multi-disciplinary Task Force, which considered the volume and consistency of the evidence and the generalizability and clinical impact of the recommendations.

Rating Scheme for the Strength of the Recommendations

Grades of Recommendation

"Some" means the recommendation considered at least one adequate scientific study, which reported that a treatment was effective. The Division recognizes that further research is likely to have an impact on the strength of the medical evidence.

"Good" means the recommendation considered the availability of multiple adequate scientific studies or at least one relevant high-quality scientific study, which reported that a treatment was effective. The Division recognizes that further research may have an impact on the strength of the medical evidence.

"Strong" means the recommendation considered the availability of multiple relevant and high quality scientific studies, which arrived at similar conclusions about the effectiveness of a treatment. The Division recognizes that further research is unlikely to have an important impact on the

strength of the medical evidence.

Cost Analysis

The guideline developers reviewed published cost analyses.

Method of Guideline Validation

External Peer Review

Internal Peer Review

Description of Method of Guideline Validation

After the internal panel/task force draft is complete it goes to an extensive external expert panel for review and response.

Advisory Panel

The Guidelines update process includes an additional review, conducted by an Advisory Panel and other advisory bodies that may consist of past Task Force members and knowledgeable professionals representing medical specialty organizations, associations, and other stakeholder groups. Professionals representing adjunct aspects of patient care, such as Risk Managers, Case Managers, and Insurers, are also included in this stage. The purpose of the external review is to provide additional sources of expertise in order to finalize draft guideline material developed by the Task Force.

Solicitation of Public Commentary

An active, open process to solicit public commentary on a year-round basis is in place in order to maximize community-based physician input and support. Contact with Accredited Providers is done through direct mailings and at Accreditation seminars.

Post Task Force Questionnaire

A survey will be sent to all Task Force members once the updated draft guidelines are completed. The survey will rate Task Force participants' satisfaction with the processes used, and evaluate Division personnel and performance. Information may be used to improve future Task Force processes.

Evidence Supporting the Recommendations

Type of Evidence Supporting the Recommendations

The type of evidence supporting the recommendations is not specifically stated.

Only randomized controlled trials or meta-analyses were used for evidence statements regarding treatment.

Benefits/Harms of Implementing the Guideline Recommendations

Potential Benefits

Optimal medical and functional outcomes for workers with a lower extremity injury

Evidence of benefits of specific treatment interventions is reviewed in the relevant sections of the original guideline document and in the evidence summary companion document (see the "Availability of Companion Documents" field).

Potential Harms

- Injuries, side effects, or infections from therapeutic injections
- Side effects and drug interactions from medications
- Complications from operative procedures
- Injury from device or component failure

Refer to specific sections of the "Major Recommendations" field and original guideline document for detailed descriptions of potential harms.

Contraindications

Contraindications

- Peripheral vascular disease, lower extremity neuropathy and diabetes are all relative contraindications to extracorporeal shock wave therapy.
- General contraindications to therapeutic injections include local or systemic infection, bleeding disorders, allergy to medications used, and patient refusal. Specific contraindications may apply to individual injections.
- Potential contraindications for the use of all steroids include hypertension, diabetes, glaucoma, and peptic ulcer disease.
- A patellofemoral arthroplasty is generally contraindicated if there is patellofemoral instability or malalignment, tibiofemoral mechanical malalignment, fixed loss of knee motion (greater than 10 degrees extension or less than 110 degrees flexion), inflammatory arthritis, and other systemic related issues.
- Celecoxib is contraindicated in sulfonamide allergic patients.
- Contraindications to tranexamic acid include patients with hypercoagulable states, cardiac stents, previous strokes.
- Relative contraindications to many surgical procedures include severe osteoporosis, obesity, smoking, diabetes, immunosuppressive disease, general disability due to other medical conditions, and psychiatric issues.
- Multi-compartmental degeneration is a contraindication to osteotomy. High body mass is a relative contraindication.
- General contraindications for grafts and transplants are individuals with obesity, inflammatory or osteoarthritis with multiple chondral defects, associated ligamentous or meniscus pathology, or who are older than 55 years of age.

See specific sections of the original guideline document for additional contraindications.

Qualifying Statements

Qualifying Statements

- This document has been prepared by the Colorado Department of Labor and Employment, Division of Workers' Compensation (Division) and should be interpreted within the context of guidelines for physicians/providers treating individuals qualifying under Colorado's Workers' Compensation Act as injured workers with lower extremity involvement.
- Although the primary purpose of this document is advisory and educational, these guidelines are enforceable under the Workers' Compensation Rules of Procedure, 7 CCR 1101-3. The Division recognizes that acceptable medical practice may include deviations from these guidelines, as individual cases dictate. Therefore, these guidelines are not relevant as evidence of a provider's legal standard of professional care.
- To properly utilize this document, the reader should not skip nor overlook any sections.
- The Division provides procedures to implement medical treatment guidelines and to foster communication to resolve disputes among the provider, payer, and patient through the Workers' Compensation Rules of Procedure. In lieu of more costly litigation, parties may wish to seek administrative dispute resolution services through the Division or the Office of Administrative Courts.

Implementation of the Guideline

Description of Implementation Strategy

Description of Implementation Strategy

The principles summarized in this section are key to the intended implementation of all Division of Workers' Compensation guidelines and critical to the reader's application of the guidelines in this document.

1. Application of the Guidelines. The Division provides procedures to implement medical treatment guidelines and to foster communication to resolve disputes among the provider, payer, and patient through the Workers' Compensation Rules of Procedure. In lieu of more costly litigation, parties may wish to seek administrative dispute resolution services through the Division or the Office of Administrative Courts.
2. Education. Education of the patient and family, as well as the employer, insurer, policy makers and the community should be the primary emphasis in the treatment of chronic pain and disability. Currently, practitioners often think of education last, after medications, manual therapy, and surgery. Practitioners must implement strategies to educate patients, employers' insurance systems, policy makers and the community as a whole. An education-based paradigm should always start with inexpensive communication providing reassuring and evidence-based information to the patient. More in-depth patient education is currently a component of treatment regimens which employ functional, restorative, preventive, and rehabilitative programs. No treatment plan is complete without addressing issues of individual and/or group patient education as a means of facilitating self-management of symptoms and prevention.
3. Informed Decision Making. Providers should implement informed decision making as a crucial element of a successful treatment plan. Patients, with the assistance of their health care practitioner, should identify their personal and professional functional goals of treatment at the first visit. Progress towards the individual's identified functional goals should be addressed by all members of the health care team at subsequent visits and throughout the established treatment plan. Nurse case managers, physical therapists, and other members of the health care team play an integral role in informed decision making and achievement of functional goals. Patient education and informed decision making should facilitate self-management of symptoms and prevention of further injury.
4. Treatment Parameter Duration. Time frames for specific interventions commence once treatments have been initiated, not on the date of injury. Obviously, duration will be impacted by patient compliance, as well as availability of services. Clinical judgment may substantiate the need to accelerate or decelerate the time frames discussed in this document.
5. Active Interventions. Active interventions emphasizing patient responsibility, such as therapeutic exercise and/or functional treatment, are generally emphasized over passive modalities, especially as treatment progresses. Generally, passive interventions facilitate progress in an active rehabilitation program with concomitant attainment of objective functional gains.
6. Active Therapeutic Exercise Program. Goals should incorporate patient strength, endurance, flexibility, coordination, and education. This includes functional application in vocational or community settings.
7. Positive Patient Response. Results are defined primarily as functional gains that can be objectively measured. Objective functional gains include, but are not limited to, positional tolerances, range of-motion (ROM), strength, and endurance, activities of daily living (ADL), cognition, psychological behavior, and efficiency/velocity measures. Subjective reports of pain and function should be considered and given relative weight when the pain has anatomic and physiologic correlation. Anatomic correlation must be based on objective findings. Re-evaluation of Treatment Every 3 to 4 Weeks. If a given treatment or modality is not producing positive results within 3 to 4 weeks, the treatment should be either modified or discontinued. Before discontinuing the treatment, the provider should have a detailed discussion with the patient to determine the reason for failure to produce positive results. Reconsideration of diagnosis should also occur in the event of poor response to a seemingly rational intervention.
8. Surgical Interventions. Surgery should be contemplated within the context of expected functional outcome and not purely for the purpose of pain relief. The concept of "cure" with respect to surgical treatment by itself is generally a misnomer. All operative interventions must be based upon positive correlation of clinical findings, clinical course, and diagnostic tests. A comprehensive assimilation of these factors must lead to a specific diagnosis with positive identification of pathologic condition(s).
9. 6-Month Time Frame. The prognosis drops precipitously for returning an injured worker to work once he/she has been temporarily totally disabled for more than 6 months. The emphasis within these guidelines is to move patients along a continuum of care and return to work within a 6-month time frame, whenever possible. It is important to note that time frames may not be pertinent to injuries that do not involve work-time loss or are not occupationally related.
10. Return-to-Work. Return-to-work is therapeutic, assuming the work is not likely to aggravate the basic problem or increase long-term pain. The practitioner must provide specific physical limitations and the patient should never be released to non-specific and vague descriptions such as "sedentary" or "light duty." The following physical limitations should be considered and modified as recommended: lifting, pushing, pulling, crouching, walking, using stairs, bending at the waist, awkward and/or sustained postures, tolerance for sitting or standing, hot and cold environments, data entry and other repetitive motion tasks, sustained grip, tool usage and vibration factors. Even if there is residual chronic pain, return-to-work is not necessarily contraindicated. The practitioner should understand all of the physical demands of the patient's job position before returning the patient to full duty and should request clarification of the patient's job duties. Clarification should be obtained from the employer or, if necessary, from including, but not limited to, an occupational health nurse, occupational therapist, vocational rehabilitation specialist, an industrial hygienist, or another professional.
11. Delayed Recovery. Strongly consider a psychological evaluation, if not previously provided, as well as initiating interdisciplinary

rehabilitation treatment and vocational goal setting, for those patients who are failing to make expected progress 6 to 12 weeks after an injury. The Division recognizes that 3% to 10% of all industrially injured patients will not recover within the timelines outlined in this document despite optimal care. Such individuals may require treatments beyond the timelines discussed within this document, but such treatment will require clear documentation by the authorized treating practitioner focusing on objective functional gains afforded by further treatment and impact upon prognosis.

12. Guideline Recommendations and Inclusion of Medical Evidence. *All recommendations are based on available evidence and/or consensus judgment.* When possible, guideline recommendations will note the level of evidence supporting the treatment recommendation. It is generally recognized that early reports of a positive treatment effect are frequently weakened or overturned by subsequent research. When interpreting medical evidence statements in the guideline, the following apply:

- Consensus means the opinion of experienced professionals based on general medical principles. Consensus recommendations are designated in the guideline as "generally well accepted," "generally accepted," "acceptable/accepted," or "well-established."
- "Some evidence" means the recommendation considered at least one adequate scientific study, which reported that a treatment was effective. The Division recognizes that further research is likely to have an impact on the strength of the medical evidence.
- "Good evidence" means the recommendation considered the availability of multiple adequate scientific studies or at least one relevant high-quality scientific study, which reported that a treatment was effective. The Division recognizes that further research may have an impact on the strength of the medical evidence.
- "Strong evidence" means the recommendation considered the availability of multiple relevant and high quality scientific studies, which arrived at similar conclusions about the effectiveness of a treatment. The Division recognizes that further research is unlikely to have an important impact on the strength of the medical evidence.

All recommendations in these guidelines are considered to represent reasonable care in appropriately selected cases, regardless of the level of evidence or consensus statement attached to it. Those procedures considered inappropriate, unreasonable, or unnecessary are designated in the guideline as "*not recommended*."

13. Care beyond Maximum Medical Improvement (MMI). MMI should be declared when a patient's condition has plateaued to the point where the authorized treating physician no longer believes further medical intervention is likely to result in improved function. However, some patients may require treatment after MMI has been declared in order to maintain their functional state. The recommendations in this guideline are for pre-MMI care and are not intended to limit post-MMI treatment.

The guideline document should be interpreted within the parameters of these guidelines principles that may lead to more optimal medical and functional outcomes for injured workers.

Institute of Medicine (IOM) National Healthcare Quality Report Categories

IOM Care Need

Getting Better

Living with Illness

IOM Domain

Effectiveness

Patient-centeredness

Identifying Information and Availability

Bibliographic Source(s)

Adaptation

Not applicable: The guideline was not adapted from another source.

Date Released

2016 Mar 16

Guideline Developer(s)

Colorado Division of Workers' Compensation - State/Local Government Agency [U.S.]

Source(s) of Funding

Colorado Division of Workers' Compensation

Guideline Committee

Not stated

Composition of Group That Authored the Guideline

Not stated

Financial Disclosures/Conflicts of Interest

Financial disclosures are on file.

Guideline Status

This is the current release of the guideline.

This guideline updates a previous version: Colorado Division of Workers' Compensation. Lower extremity injury medical treatment guidelines. Denver (CO): Colorado Division of Workers' Compensation; 2009 Jun 24. 136 p.

This guideline meets NGC's 2013 (revised) inclusion criteria.

Guideline Availability

Available from the [Colorado Division of Workers' Compensation Web site](#) .

Availability of Companion Documents

The following are available:

- Lower extremity injury medical treatment guidelines. Referenced version. Denver (CO): Colorado Division of Workers' Compensation; 2016 Mar 16. 264 p. Available from the [Colorado Division of Workers' Compensation Web site](#) .

- Search terms - lower extremity injury medical treatment guidelines. Denver (CO): Colorado Division of Workers' Compensation; 2016. 4 p. Available from the [Colorado Division of Workers' Compensation Web site](#) .
- Evidence summary: lower extremity injury medical treatment guidelines. Denver (CO): Colorado Division of Workers' Compensation; 2016. 72 p. Available from the [Colorado Division of Workers' Compensation Web site](#) .
- General literature search strategy for medical treatment guidelines. Denver (CO): Colorado Division of Workers' Compensation. 1 p. Available from the [Colorado Division of Workers' Compensation Web site](#) .
- Division of Workers' Compensation medical treatment guidelines—methodology. Denver (CO): Colorado Division of Workers' Compensation. 10 p. Available from the [Colorado Division of Workers' Compensation Web site](#) .

In addition, related critiques are available from the [Colorado Division of Workers' Compensation Web site](#) . Assessment criteria for critiques are also available from the [Colorado Division of Workers' Compensation Web site](#) .

Patient Resources

None available

NGC Status

This NGC summary was completed by ECRI Institute on April 24, 2013. The information was verified by the guideline developer on May 24, 2013. This summary was updated by ECRI Institute on October 28, 2013 following the U.S. Food and Drug Administration advisory on Acetaminophen. This summary was updated by ECRI Institute on December 22, 2016. The updated information was verified by the guideline developer on January 10, 2017.

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