Low Back Pain

Montana Utilization and Treatment Guidelines

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Presented by:
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Department of Labor and Industry
EMPLOYMENT RELATIONS DIVISION

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B. General Guideline Principles

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

1. APPLICATION OF GUIDELINES The Department provides procedures to implement medical treatment guidelines and to foster communication to resolve disputes among the providers, payers, and patients through the Administrative Rules of Montana in lieu of more costly litigation, parties may wish to request an independent medical review from the Department's Medical Director prior to submitting a Petition for a Workers' Compensation Mediation Conference.

2. 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 low back pain and disability. An education-based paradigm should start with communication providing reassuring information to the patient. A more in-depth education within a treatment regime employing functional restorative and innovative programs of prevention and rehabilitation is optimal. A treatment plan should address issues of individual and/or group patient education as a means of facilitating self-management of symptoms and prevention.

3. TREATMENT PARAMETER DURATION Timeframes 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 timeframes discussed in this document.

4. 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 are viewed as a means to facilitate progress in an active rehabilitation program with concomitant attainment of objective functional gains.

5. ACTIVE THERAPEUTIC EXERCISE PROGRAM Exercise program goals should incorporate patient strength, endurance, flexibility, coordination, and education. This includes functional application in vocational or community settings.

6. FUNCTIONAL IMPROVEMENT GOALS should be consistently addressed. 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, endurance activities of daily living cognition, psychological behavior, and efficiency/velocity measures that can be quantified. 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.

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7. 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. 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 conditions.

9. SIX-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 six months. The emphasis within these guidelines is to move patients along a continuum of care and return to work within a six-month timeframe, whenever possible. It is important to note that timeframes may not be pertinent to injuries that do not involve work-time loss or are not occupationally related.

10. 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 written physical limitations and the patient should be released to return to work with specific physical activity limitations clearly spelled out per the specific job requirement. Release to "sedentary" or "light duty" is not a specific physical limitation. The following physical limitations should be considered and modified as recommended: lifting, pushing, pulling, crouching, walking, using stairs, overhead work, 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, including, but not limited to, a health care professional with ergonomic experience, an occupational health nurse, a physical therapist, an occupational therapist, a vocational rehabilitation specialist, or an industrial hygienist.

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 Department 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 limits 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
Guidelines are recommendations based on available evidence and/or consensus recommendations. When possible, guideline recommendations will note the level of evidence supporting the treatment recommendation. 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,"* or *"well-established."*
"*Some*" means the recommendation considered at least one adequate scientific study, which reported that a treatment was effective.
"*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.
"*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.
All recommendations in the guideline are considered to represent reasonable care in appropriately selected cases, regardless of the level of evidence 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)** 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.

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C. Overview of Care

Low back pain is a ubiquitous condition with a lifetime prevalence of 84% and a high recurrence rate. However, only about 15% of the population has severe pain with functional/disability limitations. Low back pain in the workers' compensation population usually occurs from strain injuries or degenerative conditions aggravated by work. Thus, the expectation is that most low back pain will respond to therapy and self-management, and not require invasive measures.

C.1 Low Back Pain without Radicular Pain or Neurologic Findings

Multiple studies confirm the importance of the first visit and the need to follow a specific process in caring for the most common low back pain patients. It is important to perform a thorough neurological evaluation to clarify a specific diagnosis. Initial treatment should be similar for all low back pain patients who do not have progressive neurologic deficits or "red flag" signs, such as cauda equina syndrome, foot drop, or evidence of epidural abscess. Back strains as well as disc herniations and spinal stenosis aggravations without progressive neurological findings can initially be treated conservatively. However, those with any radicular findings will require close follow up and repeated neurological examinations. Refer to Section C.2. Low Back Pain with Radicular Pain and Other Neurological Findings.

A careful and detailed history and neurological exam should be done at the initial visit and repeated periodically to assess for any signs of progressive or continuing weakness, or myelopathy. All care begins with patient education and presentation of treatment options for informed decision making. In the absence of "red flag" findings or objective motor deficits, there is normally no need to order imaging for these patients. Neither injections nor surgery are usually necessary until after 6 weeks of conservative care has failed to result in adequate functional gains. At the first visit, patients with a benign clinical exam should understand the high likelihood that their condition will improve over several weeks with return to activity and some pain management. It is essential that continual neurologic exams be completed regularly to rule out disc herniations and stenosis with accompanying neurologic findings.

Providers should take a thorough history on the first visit and carefully examine the patients to identify possible "yellow flags", or conditions that predispose to more complex cases. Examples include multiple medical diagnoses, prior history of physical or emotional abuse or chronic pain, multiple unresolved musculoskeletal conditions, depression, fear-avoidant behavior, involvement in prior legal situations, drug or opioid abuse, etc. These patients may require multi-disciplinary intervention initially to avoid the development of chronic pain and the use of unnecessary diagnostic testing and prolonged treatment. Many of these issues can be identified using validated patient-completed screening tools. Patients with persistent neurologic findings will also require more progressive work-up, referral to a specialist or other treatment.

Health care providers are expected to discuss self-management of pain with their patients. Appropriate over-the-counter medication and ice or heat, if desired by the patient may initially be helpful. If pain is severe, as in some cases with ruptured discs, opioids may be prescribed for

a short time period (such as 3-7 days). This avoids the accumulation of unused opioids that may be available for others in the household to misuse and minimizes the likelihood of opioid dependence. Multiple repeat prescriptions for opioids should generally be avoided. If it is necessary to prescribe opioids for more than 14 days, the provider should do the following:

- repeat a thorough neurologic and back examination to rule out a more serious diagnosis;
- check the Montana Prescription Drug Registry;
- consider urine drug screening;
- follow the patient closely; and
- consider a short screening questionnaire for abuse risk before prescribing.

All providers should emphasize return to activity with a detailed discussion describing exactly which activities should be performed and how often, as well as those activities that should be avoided. The patient should identify functional goals at the initial visit which are specific to their needs. Examples include return to work; gardening, playing softball, driving, and computer use. In the absence of instability, complete bed rest or lumbar immobilization is not advisable for this group of patients. The discussion of functional goals and current recommended activities should lead to return to work recommendations.

Multiple studies assessing cost effectiveness and outcomes recommend the following initial interventions: education, non-opioid pain medication, and exercise or active therapy. Spinal manipulation and supervised physical therapy, often including directional preference treatment, may also be appropriate for some patients. The majority of patients will recover with these interventions. Return to activity is important and should include return to work at appropriate physical duty levels, possibly with reduced work hours.

It is also appropriate to address smoking, as there is some evidence that patients who smoke respond less well to non-operative spine care and that quitting smoking results in greater improvement.

Given the high recovery rate for low back pain in the general population, the need for referral to physical therapy frequently depends on the presence of “yellow flags” and the need for further patient education to sustain activity participation. “Yellow flags” generally refer to psychosocial issues such as problems with supervisors, presence of depression or anxiety, social withdrawal, fear-avoidance beliefs (that activity causing pain is harmful) or belief that passive therapy alone is curative. However, one study noted decreased overall costs for low back pain if a patient is referred early to physical therapy. Another well-done study provides some evidence that referral of patients in the first weeks of uncomplicated low back pain adds little to the otherwise favorable prognosis for acute low back pain and does incur additional short-term costs of care. This study did not consider direct disability costs nor the effect on return to work. Injured workers may benefit from at least 2 visits with a physical therapist to reinforce return to activity and education regarding exercise and activity. Further visits may be necessary if return to restricted duty cannot be arranged; and to reinforce education regarding exercise and activity. Patients with evidence of fear avoidant behavior or other “yellow flags” are likely to require a

different physical and/or psychosocial approach. Refer to the Department's Chronic Pain Disorder Guideline.

The long-term recovery is good (approximately 80% recovery in six weeks) for both those with radicular symptoms (usually without motor deficits) and those without radicular symptoms. Measuring the centimeter difference between the tip of the fingers and the floor in forward flexion can be a good measure of progress. In one study, this factor was directly related to results on the Roland Morris Scale at one month and one year. This measure is probably more predictive of outcome for true radicular patients. At one month, the finger to floor distance is usually reduced by 50%.

Many patients with musculoskeletal disorders also experience anxiety or depression. Using accepted screening tools periodically during visits can identify early psychological concerns. Cognitive behavioral therapy (CBT) is recommended for these patients and others who are not progressing well due to fear avoidance factors. CBT is as effective in disability populations as those without disability.

It is generally not appropriate to perform invasive procedures on a patient who reports only mild back pain, for example 3 points on a 10-point Visual Analog Scale (VAS) measurement. However, pain reports vary greatly among individuals with the same condition. Therefore providers should also consider any persistent compromise of physical function after compliance with recommended initial treatment. The following are examples of functional compromise: difficulty with activities of daily living, inability to participate in the recommended active therapy or lack of progress in job duty requirements.

Spinal injections are unlikely to provide long-term relief for conditions such as sacroiliac (SI) joint, facet dysfunction or stenosis. Spinal injections should not be done without prior imaging to establish the diagnosis. The risks versus benefits must be carefully weighed and discussed with the patient when these interventions are considered. Both the specialist referred to and the authorized provider must thoroughly discuss and document the possible complications, the limited short-term benefits, and the need for continuing engagement in active therapy.

Imaging is not recommended for at least 6 weeks after the initial injury unless it is necessary prior to a spinal injection or to rule out other acute diagnoses such as fracture, occult cancer, infection, lower extremity weakness, or signs of myelopathy. If a patient has persistent pain and imaging is deemed necessary, the ordering provider should document the following elements from face-to-face discussion with the patient:

- the specific findings that the provider is trying to rule out with imaging and how the diagnostic test will influence treatment, and
- the lack of importance of "degenerative disease" alone due to its frequent occurrence in asymptomatic patients.

Providers should remember that many medical terms used to describe radiographic findings or used as diagnostic terms engender fear and concern in patients. Unexplained concerns can lead patients to believe they have a significant pathological condition when in fact, their condition is common and rarely leads to significant functional changes.

Surgery is usually not necessary in these patients, except in cases of symptomatic spinal instability, usually grade 2 spondylolisthesis. Refer to G. Therapeutic Procedures – Operative for more details.

C.2 Low Back Pain with Radicular Pain or Other Neurologic Findings

Radicular findings from a herniated disc without progressive neurological findings, cauda equina symptoms, and/or without obvious significant continuing weakness should be treated initially according to the previous section. Seventy per cent of patients with radicular pain and non-surgical treatment are likely to have marked reduction in pain at 4 weeks with a 60% return to work. After 8 months, over 90% would be expected to have an excellent outcome and return to work. About 20% will have a recurrence of symptoms. When directional preference testing is done, centralization tends to predict a favorable course with non-surgical treatment.
Most patients should exhibit the following signs of radiculopathy before invasive procedures are considered:

- pain in the legs greater than in the back which interferes with function, return to work and/or active therapy; and
- physical exam findings of abnormal reflexes, motor weakness, or radicular sensation deficits; and
- findings on the magnetic resonance imaging (MRI) which indicate impingement of nerves or the spinal cord corresponding to reproducible physical exam findings.

Patients with disc herniation and associated foot drop or cauda equina syndrome require early imaging and surgical intervention. Any patient with neurologic findings of significant weakness or significant functional impairment at 6 weeks should be considered for surgical referral since surgery should be performed before 12 weeks in order to assure the best outcome.

Spinal injections have not been shown to provide long-term beneficial effects for most back pain patients with or without radicular findings. Although complications are relatively rare, they can be catastrophic; thus, the cost benefit versus risk ratio is small. Injections can contribute to the likelihood of osteoporotic fractures later in life. . They may be used in uncommon cases when a patient continues to have measurable functional deficits at 6 weeks after not making progress despite compliance with conservative treatment or for those who are incapacitated after the initial treatment for herniated discs. For further details refer to F.3. Injections – Spinal Therapeutic and/or F.4. Injections – Other (including Radio frequency).

Cases with objective findings causing functional impairment, such as stenosis with pain exacerbated by extension which causes limited ability to walk, may require surgical treatment. Herniated discs with continued neurologic findings interfering with activity may also require surgery. The need for accompanying fusion is determined by evidence of lumbar instability. Patients with symptomatic disc herniation have the best chance for a good functional outcome if operated upon with 3 months of the onset of radicular pain. In at least one large trial the initial short-term results were superior to non-operative treatment. All cases requiring surgical intervention require documentation of a discussion with the patient to clarify that functional goals such as anticipated activities of daily living (ADLs) and work status align with patient expectations and goals. Refer to G. Therapeutic Procedures – Operative for details.

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D. Initial Diagnostic Procedures

D.1 History Taking and Physical Examination (Hx & PE)

The Department recommends the following diagnostic procedures be considered the responsibility of the workers' compensation carrier, at least initially, in order to ensure that an accurate diagnosis and treatment plan can be established. Standard procedures, which should be utilized when initially diagnosing a work-related low back pain complaint, are listed below.

History Taking and Physical Examination (Hx and PE) are generally accepted, well-established and widely used procedures that establish the basis for and dictate subsequent stages of diagnostic and therapeutic procedures. When findings of clinical evaluations and those of other diagnostic procedures do not complement each other, the objective clinical findings should have preference. The medical records should reasonably document the following.

D.1.a History of Present Injury

A detailed history, taken in temporal proximity to the time of injury should primarily guide evaluation and treatment. The history should include:

1. Mechanism of injury: This includes details of symptom onset and progression, including a detailed description and the position of the body before, during, and at the end of the incident. In the absence of a known specific incident, common positioning of the body during the work day and frequency of requirements such as lifting, pushing, and pulling should be included.
2. Description of pain: This should include location of pain, nature of symptoms, and alleviating/exacerbating factors (e.g. sleep positions, sitting tolerance). The presence of pain at night or while at rest may be a sign of more extensive pathology. The history should include both the primary and secondary complaints (e.g., primary low back pain, secondary hip, or groin). Pain should be quantified on a Visual Analog Scale (VAS). The use of a patient-completed pain drawing is highly recommended, especially during the first two weeks following injury, to assure that all work-related symptoms are being addressed. Screening the patient for fear-avoidance issues regarding recurrent pain may be useful initially to guide treatment.
3. Functional assessment: Functional ability should be assessed and documented at the beginning of treatment. Periodic assessment should be recorded throughout the course of care to follow the trajectory of recovery. In addition to being more relevant to recovery from low back pain, functional measures are likely to be more reliable over time than pain measures. In one study of patients with lumbar spinal stenosis, functional measures such as the Oswestry Disability Index (ODI), the Swiss Spinal Stenosis Scale and the Patient Specific Functional Scale demonstrated test-retest reliability.

Patient-reported outcomes, whether of pain or function, are susceptible to a phenomenon called response shift. This refers to changes in self-evaluation which may accompany changes in health status. Patient self-reports may not coincide with objective measures of outcome, such as straight

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leg raising, due to reconceptualization of the impact of pain on daily function and internal recalibration of pain scales.
Response shift has potential to obscure treatment effects in clinical trials and clinical practice, and may lead to apparent discrepancies in patient-reported outcomes following treatment interventions. While methods of measuring and accounting for response shift are not yet fully developed, understanding that the phenomenon exists can help clinicians understand what is happening when some measures of patient progress appear inconsistent with other measures of progress.

1. Presence and distribution of lower extremity numbness, paresthesias, or weakness, especially if precipitated by coughing or sneezing.
2. Alteration in bowel, bladder, or sexual function; and for female patients, alteration in their menstrual cycle.
3. Prior occupational and non-occupational injuries to the same area, including specific prior treatment, chronic or recurrent symptoms, and any functional limitations. Specific history regarding prior motor vehicle accidents may be helpful.
4. Ability to perform job duties and activities of daily living (ADLs) including the ability to maintain balance and walk rapidly without difficulty.

D.1.b Past History

1. Past medical includes neoplasm, gout, arthritis, hypertension, kidney stones, diabetes, and fractures;
2. Review of systems includes symptoms of rheumatologic, neurologic, endocrine, neoplastic, infectious, and other systemic diseases;
3. Type 1 or Type 2 diabetes. People with a body-mass index (BMI) greater than 30 may be at risk for the disease;
4. Smoking history – smoking appears to be related to low back pain and may predispose patients to opioid addiction;
5. Medication use - prescription and non-prescription including vitamins and natural products;
6. Vocational and recreational pursuits, including military service; and
7. History of depression, anxiety, or other psychiatric illness.

D.1.c Physical Examination

Physical Examination should include accepted tests and exam techniques applicable to the area being examined, including:

1. General inspection, including stance and gait;
2. Visual inspection;
3. Palpation;
4. Lumbar range of motion preferably measured or quantified range of motion, quality of motion, and presence of muscle spasm. Motion evaluation of specific joints may be indicated;
5. Examination of cervical, thoracic and lumbar spine, pelvis, and lower extremities;

6. Nerve tension testing. Both the straight leg raising test and the slump test can be used to reproduce symptoms and are highly reproducible and correlated. Symptoms usually occur at around 50 degrees of flexion and are exacerbated by ankle dorsiflexion. The slump test is a straight leg raise performed with the patient in a seated slumped forward posture, neck flexed and arms behind the back. A positive contralateral straight leg raising is quite specific, although less sensitively for disc herniation;
7. Sensory and motor examination of the lower extremities with specific nerve root focus;
8. Deep tendon reflexes with or without Babinski's;
9. For providers trained in the technique, repeated end range testing to establish the presence of a directional preference;
10. A combination of multiple physical exam test results is preferred as none are independently diagnostic;
11. If applicable to injury, anal sphincter tone and/or perianal sensation; and
12. If applicable, abdominal examination, vascular examination, circumferential lower extremity measurements, or evaluation of hip or other lower extremity abnormalities;
13. If applicable, Waddell Signs, which include five categories of clinical signs (1) tenderness: superficial and non-anatomic, (2) pain with simulation: axial loading and rotation, (3) regional findings: sensory and motor, inconsistent with nerve root patterns (4) distraction/inconsistency in straight leg raising findings, and (5) over-reaction to physical examination maneuvers. Significance may be attached to positive findings in three out of five of these categories, but not to isolated findings. Waddell advocates considering Waddell's signs prior to recommending a surgical procedure. These signs should be measured routinely to identify patients requiring further assessment (i.e., biopsychosocial) prior to undergoing back surgery.

It is generally agreed that Waddell Signs are associated with decreased functional performance and greater subjective pain levels, though they provide no information on the etiology of pain. Waddell Signs cannot be used to predict or diagnose malingering. The presence of three out of five signs may most appropriately be viewed as a "yellow flag," or screening test, alerting clinicians to those patients who require a more comprehensive approach to their assessment and care plan. Therefore, if three out of five Waddell Signs are positive in a patient with subacute or chronic back pain, a psychosocial evaluation should be part of the total evaluation of the patient. Waddell's signs were researched on American and Western European populations; thus the results may not be applicable to cultures with differing concepts of pain. Refer to Section E.2.c. Personality/Psychological/Psychosocial Evaluation.

D.1.d Relationship to Work

Relationship To Work includes a statement of the probability that the illness or injury is work-related. If further information is necessary to determine work relatedness, the physician should clearly state what additional diagnostic studies or job information is required.

<u>Principles of Causation of Occupational Low Back Pain</u>
Causation is a medical/legal analysis in the workers compensation system. The information in

the Medical Treatment Guidelines pertaining to causation addresses only the evidence related to the medical analysis of causation. Actual cases may vary from the evidence presented based on specific circumstances of the claim. Work-related conditions may occur from the following:

- a specific incident or injury,
- aggravation of a previous symptomatic condition,
- occupational disease arising out of events occurring on more than a single work day or work shift, or
- a work-related exposure that renders a previously asymptomatic condition symptomatic and subsequently requires treatment.

All of these conditions must be determined based on the specifics of the work related injury or exposure. The clinician determines the need for treatment due to the work related event. Most low back cases result from injuries. It must also be acknowledged that many of the studies reviewed reflect only the symptom of back pain.

Low back pain frequently does not have a clear diagnosis agreed upon by all examiners. Whether a patient's low back pain results from sacro-iliac joint dysfunction, lumbar axial pain, or facet dysfunction is difficult to reliably determine. Therefore, the studies reviewed were chosen because they identified low back pain as chronic or causing disability. To apply the below standards, the clinician must first make a relatively specific low back pain diagnosis which is substantiated by consistent physical exam findings. The following information was reviewed using evidence based standards to address the effects on workers of cumulative exposures and should only be considered in that context. The clinician should use this information judiciously.

There is good evidence from a systematic review that standing and walking do not cause low back pain, and good evidence that sitting does not cause low back pain. Thus, while some of these activities may aggravate low back pain, there is no evidence that they are primarily causative in a cumulative manner. In addition clinicians normally prescribe alternating walking, sitting and standing for workers with low back pain complaints.

Most work tasks involve more than one risk factor. Due to the variety of study methods it is difficult to set reliable measurements for determining the exact risk. Multiple epidemiological studies verify an association between low back pain and patient transfer activities, logging and other professions requiring heavy lifting with flexion or with rotation. National Institute for Occupational Safety and Health (NIOSH) and other organizations focusing on ergonomics suggest that heavy lifting be limited and performed in the least stressful physiologic manner.

A number of systematic reviews attempted to identify isolated factors regarding low back pain. One reported conflicting evidence regarding bending, twisting, lifting, or pushing/pulling and also multiple studies not showing a convincing relationship to manual handling/assisting patients. The variety of studies involved, the lack of precision regarding actual numbers of lifts, weight of lifts, body position and the goal of studying risk factors in isolation have led to this conflicting literature.

A full review of the literature indicates that more than one risk factor is involved in cumulative low back pain. There is some evidence that high physical workloads are associated with sciatica in working populations, either as primary causes or as triggers of the development of nerve root symptoms. There is good evidence that trunk flexion, rotation and lifting in the work place cumulatively is associated with low back pain. There is some evidence that exposures of seven hours per week or greater, over more than 9.5 years is associated with low back pain in an apparent dose response relationship. A well done prospective cohort study documented cumulative exposure and incidence of low back pain. The study found high levels of cumulative low back loads combined with high lifting peak loads to be a significant risk for low back pain. Lifting 150 foot/pounds, 50 times per week is associated with low back pain. This corresponds with a 50-pound 3-foot lift 10 times per day. Lifting greater than 50-55 pounds, 15 times per day and flexion at 60º or more, more than 5% per day are associated with low back pain. Thus, the combination of flexion and lifting 50 pounds or more repetitively is a cumulative risk factor for low back pain.

Given conflicting evidence regarding lifting alone, it would appear that the best evidence exists to support a combination of regular heavy lifting and bent posture as cumulatively causing low back pain. Applying the totality of evidence, it would appear that heavier lifting, 25 kilograms or 50-55 pounds and higher, may be considered a risk factor for cumulative low back pain, when combined with flexion and performed 10-15 times per day over cumulative years of exposure.

Numerous studies have failed to show a relationship between whole body vibration (WBV) and degenerative changes of the lumbar spine seen on imaging studies. WBV has not been established as a cause of spinal disorders. There is some evidence that WBV has no important association with disc pathology in the lumbar spine in professional drivers. It is unclear whether WBV has an effect on low back pain. Clinicians will need to make case specific decisions in this area.

Risk Factors of Non-Occupational Low Back Pain

The majority of studies also report BMI greater that 25 as a risk factor for low back pain. Smoking has been modestly associated with low back pain. The relationship of genetics to low back pain is unclear, although genetics may play a more important role in the upper lumbar and thoracic spine, L3 and above. Most low back cases with significant impairment occur in the lower levels of the lumbar spine.

Clinicians should be well versed on the non-predictive value of degenerative imaging findings as noted in section E.1. Imaging Studies. Numerous studies have validated the finding of degenerative changes in older asymptomatic individuals. The presence of these findings cannot be used to justify an argument that back pain in a specific individual was inevitable and not due to work related exposures.

D.2 Radiographic Imaging

Radiographic imaging of the lumbosacral spine is a generally accepted, well-established, and widely used diagnostic procedure when specific indications based on history and/or physical examination are present. There is some evidence that early radiographic imaging without clear indications is associated with prolonged care, although it does not change functional outcomes. Therefore, it should not be routinely performed without indications. The mechanism of injury and specific indications for the radiograph should be listed on the request form to aid the radiologist and x-ray technician. Suggested indications include:

1. History of significant trauma, especially blunt trauma or fall from a height;
2. Age over 55 years;
3. Suspicion of fracture, dislocation, instability, or objective evidence of neurologic deficit;
4. Unexplained or persistent low back pain for at least 6 weeks or pain that is worse with rest;
5. Localized pain, fever, constitutional symptoms, or history or exam suggestive of intravenous drug abuse, prolonged steroid use, or osteomyelitis;
6. Suspected lesion in the lumbosacral spine due to tumor or systemic illness, such as a rheumatic/rheumatoid disorder or endocrinopathy. Suspected lesions may require special views;
7. Flexion and extension views to evaluate instability; and
8. Past medical history suggestive of pre-existing spinal disease, osteoporosis, spinal instrumentation, or cancer;
9. Optionally, prior to any manipulative treatment.

D.3 Laboratory Testing

Laboratory tests are generally accepted, well-established, and widely used procedures. They are, however, rarely indicated at the time of initial evaluation, unless there is suspicion of systemic illness, infection, neoplasia, underlying rheumatologic disorder, or connective tissue disorder based on history and/or physical examination. Laboratory tests can provide useful diagnostic information. Furthermore, they may assist the provider in determining the best course of treatment for the injured worker. Tests include, but are not limited to:

1. Complete blood count (CBC) with differential, which can detect infection, blood dyscrasias, and medication side effects;
2. Blood-glucose level, which can be used to detect evidence of Type I or Type 2 diabetes;
3. Erythrocyte sedimentation rate (ESR), rheumatoid factor (RF), anti-nuclear antigen (ANA), human leukocyte antigen (HLA), and C-reactive protein (CRP), which can be used to detect evidence of a rheumatologic, infectious, or connective tissue disorder;
4. Serum calcium, phosphorous, uric acid, alkaline phosphatase, and acid phosphatase, vitamin D levels, which can detect bone disease;
5. Urinalysis for bacteria (usually with culture and sensitivity), calcium, phosphorus, hydroxyproline, or hematuria; and
6. Liver and kidney function which may be performed for prolonged anti-inflammatory use or other medications requiring monitoring

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E. Follow-Up Diagnostic Imaging and Testing Procedures

One diagnostic imaging procedure may provide the same or distinctive information as does another procedure. Therefore, the prudent choice of a single diagnostic procedure, a complement of procedures, or a sequence of procedures will optimize diagnostic accuracy; maximize cost effectiveness (by avoiding redundancy); and minimize potential adverse effects to patients.

All imaging procedures have a degree of specificity and sensitivity for various diagnoses. No isolated imaging test can assure a correct diagnosis. Clinical information obtained by history taking and physical examination should form the basis for selecting an imaging procedure and interpreting its results.

Magnetic resonance imaging (MRI), myelography, or Computed Axial Tomography (CT) scanning following myelography may provide useful information for many spinal disorders. Practitioners should be aware of the radiation doses associated with various procedures and provide appropriate warnings to patients. Montanans have a background exposure to radiation, and unnecessary CT scans or X-rays increase the lifetime risk of cancer death.
When a diagnostic procedure, in conjunction with clinical information, can provide sufficient information to establish an accurate diagnosis, the second diagnostic procedure will become a redundant procedure. At the same time, a subsequent diagnostic procedure can be a complementary diagnostic procedure if the first or preceding procedures, in conjunction with clinical information, cannot provide an accurate diagnosis. Usually, preference of a procedure over others depends on availability, a patient's tolerance**,** and/or the treating practitioner's familiarity with the procedure.

E.1 Imaging Studies

Imaging Studies are generally accepted, well-established, and widely used diagnostic procedures. In the absence of myelopathy, progressive neurological changes, or history of cancer, imaging usually is not appropriate until conservative therapy has been tried and has failed. Six to eight weeks of treatment is frequently an adequate period of time before an imaging procedure is in order, but the clinician should use judgment in this regard. When indicated, imaging studies can be utilized for further evaluation of the low back, based on the mechanism of injury, symptoms, and patient history. Prudent choice of a single diagnostic procedure, a complementary combination of procedures, or a proper sequential order of complementary procedures, will help ensure maximum diagnostic accuracy and minimize adverse effect to the patient.

When the findings of the diagnostic imaging and testing procedures are not consistent with the clinical examination, the clinical findings should have preference. There is good evidence that in the asymptomatic population, disc bulges, disc protrusions, annular tears, high intensity zone areas, and disc height loss are prevalent 40–60% of the time, depending on the condition, study, and age of the patient. A recent study found no significant relationship between low back pain and high intensity zones of the lumbar disc, either in spatial distribution of the zone in a disc or in the number or location of discs. There is some evidence that depression is a more accurate

predictor of the development of low back pain than many common MRI findings, such as disc bulges, disc protrusions, Modic endplate changes, disc height loss, annular tears, and facet degeneration, which are common in asymptomatic persons and are not associated with the development of low back pain. Therefore, the existence of these anatomic findings should not be considered relevant without physiologic and clinical correlation in an individual patient. There is some evidence that extruded discs are uncommon in asymptomatic persons but are associated with low back pain. Small herniations and protrusions are often not pain generators, although small foraminal disc herniations are likely to compress the nerve root and require surgical removal.

The studies below are listed in frequency of use, not importance.

E.1.a Magnetic Resonance Imaging (MRI)

Magnetic Resonance Imaging is rarely indicated in patients with non-traumatic acute low back pain with no neuropathic signs or symptoms. It is generally the first follow-up imaging study in individuals who respond poorly to proper initial conservative care. MRI is useful in suspected nerve root compression, myelopathy, masses, infections, metastatic disease, disc herniation, annular tear, and cord contusion. MRI is contraindicated in patients with certain ferrous and other implants; however, MRI scanners compatible with pacemakers are now available.

In general, conventional full-size, high field magnet 1.5 to 3.0 tesla MRI provides better resolution and is preferred. A lower field scan may be indicated when a patient cannot fit into a high field scanner or is too claustrophobic despite sedation. Inadequate resolution on the first scan may require a second MRI using a different technique. All questions in this regard should be discussed with the MRI center and/or radiologist.

E.1.b Specialized MRI Scans

<u>MRI with 3-dimensional Reconstruction</u>
On rare occasions, MRI with 3-dimensional reconstruction views may be used as a pre-surgical diagnostic procedure to obtain accurate information of characteristics, location, and spatial relationships among soft tissue and bony structures.

<u>Dynamic-kinetic MRI of the Spine</u>
Dynamic-kinetic MRI of the spine uses an MRI unit configured with a top-front open design which enables upright, weight-bearing patient positioning in a variety of postures not obtainable with the recumbent images derived from conventional, closed unit MRI systems. Imaging can be obtained in flexion, extension, and rotation of the spine, as well as in erect positioning. There is a theoretical advantage to imaging sequences obtained under more physiologic conditions than in the supine position. There is currently ongoing research to establish whether the theoretical advantages of positional and kinetic MRI result in improved sensitivity and specificity in detecting spine pathology. Currently it remains investigational and is not recommended until the correlation with clinical syndromes and outcomes is firmly established.

Contrast MRI
Usually required for those with prior lumbar surgery, possible infection, possible malignancy, or tumor.

E.1.c Computed Axial Tomography (CT)

Computed Axial Tomography (CT) scans provide excellent visualization of bone and is used to further evaluate bony masses and suspected fractures not clearly identified on radiographic evaluation. It may sometimes be done as a complement to MRI scanning to better delineate bony osteophyte formation in the neural foramen. Instrument-scatter reduction software provides better resolution when metallic artifact is of concern. Unnecessary CT scanning should be avoided due to the radiation exposure contributing to cancer risk.

E.1.d Myelography

Myelography is the injection of radiopaque material into the spinal subarachnoid space, with x-rays then taken to define anatomy. It may be used as a pre-surgical diagnostic procedure to obtain accurate information of characteristics, location, and spatial relationships among soft tissue and bony structures. The use of small needles and a less toxic, water-soluble, nonionic contrast is recommended.

Myelography is an invasive procedure with numerous complications, including nausea, vomiting, headache, convulsion, arachnoiditis, cerebrospinal fluid (CSF) leakage, allergic reactions, bleeding, and infection. Therefore, myelography should be considered only in the following instances:

- when CT and MRI are unavailable;
- when CT or MRI is contraindicated such as for morbidly obese patients or those who have undergone multiple surgical procedures; **and** when other tests prove non-diagnostic in the surgical candidate.

E.1.e CT Myelogram

CT Myelogram provides more detailed information about relationships between neural elements and surrounding anatomy and is appropriate in patients with multiple prior operations, tumorous conditions, or those that cannot have MRIs due to implants, etc.

E.1.f Lineal Tomography

Lineal Tomography is infrequently used, yet may be helpful in the evaluation of bone surfaces, bony fusion, or pseudarthrosis.

E.1.g Bone Scan (Radioisotope Bone Scanning)

Bone scanning is generally accepted, well-established, and widely used. It is more sensitive but less specific than MRI. Technetium-99m diphosphonate uptake reflects osteoblastic activity and may be useful in diagnosing metastatic/primary bone tumors, occult or stress fractures, osteomyelitis, infection, and other inflammatory lesions, but it cannot distinguish between these conditions.

E.1.h Other Radioisotope Scanning

Indium and gallium scans are generally accepted, well-established, widely used procedures. and often used to diagnose lesions seen on other diagnostic imaging studies. Gallium-67 citrate scans are used to localize tumors, infections, and abscesses. Indium-111-labeled leukocyte scanning is utilized for localizing infection or inflammation and is usually not used for the lumbar spine.

E.1.i Dynamic [Digital] Fluoroscopy

Dynamic [Digital] Fluoroscopy of the lumbar spine measures the motion of intervertebral segments using a videofluoroscopy unit to capture images as the subject performs lumbar flexion and extension, storing the anatomic motion of the spine in a computer. Currently, it is not recommended for use in the diagnosis of lumbar instability because there is limited information on normal segmental motion for the age groups commonly presenting with low back pain, and diagnostic criteria for specific spinal conditions are not yet defined. No studies have yet demonstrated predictive value in terms of standard operative and non-operative therapeutic outcomes.

E.2 Other Tests

The following diagnostic procedures in this subsection are listed in alphabetical order, not by importance.

E.2.a Electrodiagnostic Testing

E.2.a.i Electromyography (EMG), Nerve Conduction Studies (NCS)

These are generally accepted, well-established, and widely used diagnostic procedures. EMG and NCS, when performed and interpreted by a trained physician/electrophysiologist, may be useful for patients with suspected neural involvement whose symptoms are persistent or unresponsive to initial conservative treatments. They are used to differentiate peripheral neural deficits from radicular and spinal cord neural deficits and to rule out concomitant myopathy. However, F-Wave latencies are not diagnostic for radiculopathy. H-reflex Studies are of value regarding S-1 radiculopathy.

In general, EMG and NCS are complementary to imaging procedures such as CT, MRI, and/or myelography or diagnostic injection procedures. Electrodiagnostic studies may provide useful,

correlative neuropathophysiological information that would be otherwise unobtainable from the radiologic studies discussed above and can assist in treatment decisions, such as the need for surgery. Generally nerve conduction studies have good sensitivity but poor specificity and a negative study can occur in the face of significant nerve entrapment.

E.2.a.ii Portable Automated Electrodiagnostic Device (also known as Surface EMG)

Portable Automated Electrodiagnostic Device (also known as Surface EMG) is not a substitute for conventional diagnostic testing in clinical decision-making, and therefore, is not recommended.

E.2.a.iii Somatosensory Evoked Potential (SSEP)

Somatosensory Evoked Potential (SSEP) is not recommended to identify radiculopathy. It may be used to evaluate myelopathy and other rare neurological disorders, such as neurogenic bladder and sexual dysfunction.

E.2.a.iv Current Perception Threshold (CPT) Evaluation

Current Perception Threshold (CPT) Evaluation may be useful as a screening tool, but its diagnostic efficacy in the evaluation of industrial low back pain has not been determined. Therefore, CPT is not recommended as a diagnostic tool.

E.2.a.v Large Array Surface Electromyography

Large Array Surface Electromyography measures low back muscle activity using a fixed array of 63 electrodes arranged in nine rows and seven columns between the seventh thoracic spinous process and the iliac crest. The array simultaneously collects myoelectric data from multifidus, iliocostalis, quadratus lumborum, and other lumbar muscles, which is analyzed for patterns of activity in these muscle groups. It is used in researching physiologic changes and adaptations to back pain, but is not recommended as a diagnostic procedure for individuals with back pain due to a lack of interpretive standards.

E.2.a.vi Surface EMG in combination with Range of Motion and/or Functional Capacity Evaluation, and/or a Comprehensive Muscular Activity Profile

These tests are designed to detect differences between persons with and without low back pain, measuring signals in lumbar flexion, which show that painful paraspinal muscles fail to relax fully. It may show aspects of the pathophysiology of muscle activity, which advance the scientific understanding of low back pain. Some versions of this test also purport to determine the significance of disc pathology and the age of an injury. It has not been evaluated in a setting with a spectrum of patients commonly seen in clinical practice, and tested against a diagnostic reference standard.

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The comprehensive muscular activity profile version of this test has been shown to correctly identify healthy subjects who have been instructed to perform at less than full effort on lifting tests from those who are performing at full effort. This aspect has not been tested within a group of low back patients. It may provide some information as to possible neurologic or musculoskeletal diagnoses, but it cannot be used alone to definitively diagnose a medical condition. It is not recommended as a diagnostic tool and cannot distinguish malingering from sub-maximal effort for other reasons, such as fear/avoidance behavior. Therefore, these tests are not suitable as a diagnostic tests for low back pain, and their use for this purpose is not recommended.

E.2.b Injections - Diagnostic

Description

Diagnostic spinal injections are established procedures. These injections may be useful for localizing the source of pain when changes in treatment would be beneficial based on the results. They may have some short-term therapeutic value. Each diagnostic injection has inherent risks, and risk versus benefit should always be evaluated when considering injection therapy.

Regarding short term benefits from injections, there is strong evidence that epidural steroid injections have a small average short term benefit for leg pain and disability for those with sciatica. Additionally, specific to transforaminal injections, there is good evidence that the addition of steroids to a transforaminal bupivacaine injection has a small effect on patient reported pain and disability.

Regarding long term benefit from injections, there is strong evidence that epidural steroid injections (ESI) do not, on average , provide clinically meaningful long-term improvements in leg pain, back pain, or disability in patients with sciatica (lumbar radicular pain or radiculopathy).

Conversely, there is some evidence that the addition of steroids to a transforaminal bupivacaine injection may reduce the frequency of surgery in the first year after treatment in patients with neurologic compression and corresponding imaging findings who also are strong candidates for surgery and have completed 6 weeks of therapy without adequate benefit. There is some evidence that the benefits for the non-surgical group persisted for at least 5 years in most patients, regardless of the type of block given. An additional study provides some evidence that after 6 weeks of conservative therapy for large herniated discs, an epidural injection may be attempted, as it does not compromise the results of a discectomy at a later date. One half of the patients in this study who were randomized to ESIs did not have surgery and this benefit persisted. Because this study did not have a control group that received neither treatment, nor a group which received injections without steroids, one cannot make definite conclusions regarding the efficacy of ESI injections in this setting.

There is strong evidence that ESI has no short or long term benefit for axial low back pain. A high quality meta-analysis provides additional good evidence against the use of lumbar facet or

epidural injections for relief of non-radicular low back pain. Facet injections have very limited therapeutic or diagnostic use. Refer to F.3.e. Zygapophyseal (Facet) Injections.

In summary, there is no proven benefit from adding steroids to local anesthetic spinal injections for most injections, with the possible exception of patients who are strong candidates for surgery based on a herniated disc and clear nerve impingement. However, steroids are currently used routinely in spinal injections due to a presumed physiologic effect.

Therapeutic spinal injections have not been proven to change the long-term course of most patients with spinal pain. They have a limited role in treatment and should be used in only a small subset of patients where the criteria below have been clearly met. Refer to specific injections as described in this section for indications.

Indications

Since these procedures are invasive, less invasive or non-invasive procedures should be considered first.. All spinal injections should be preceded by either an MRI or a CT scan. Selection of patients, choice of procedure, and localization of the level for injection should be determined by clinical information indicating strong suspicion for pathologic condition(s) from reproducible exam findings. Diagnostic blocks may be helpful when MRI or other diagnostic tests are not definitive.

The number of diagnostic procedures should be limited in any individual patient to those most likely to be primary pain generators. Patients should not receive all of the available or related diagnostic blocks listed merely in an attempt to identify 100% of the pain generators. Blocks are only appropriate if the patient is eligible for increased therapy, such as rhizotomy or active therapy, based on the results of the block.

Informed decision making should also be documented for injections and 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. The purpose of spinal injections, as well as surgery, is to facilitate active therapy by providing short-term relief through reduction of pain. Patients should be encouraged to express their personal goals, outcome expectations and desires from treatment as well as any personal habits or traits that may be impacted by procedures or their possible side effects. All patients must commit to continuing appropriate exercise with functionally directed rehabilitation, usually beginning within 7 days, at the injectionist's discretion. Since many patients with these conditions will improve significantly over time, without surgical interventions, patients must be able to make well-informed decisions regarding their treatment. All injections must be accompanied by active therapy.

The interpretation of the test results are primarily based on functional change. Symptom reports and pain responses (via a recognized pain scale) before and at an appropriate time period after the injection should also be documented. The diagnostic significance of the test result should be evaluated in conjunction with clinical information and the results of other diagnostic procedures. Injections with local anesthetics of differing duration may be used to support a diagnosis. In

some cases, injections at multiple levels may be required to accurately diagnose low back pain. Refer to F.3. Injections – Spinal Therapeutic and/or F.4. Injections – Other (Including Radio Frequency) for diagnostic information on specific injections.

It is obligatory that sufficient data be accumulated by the examiner performing this procedure such that the diagnostic value of the procedure is evident to other reviewers. This entails documentation of patient response regarding the degree and type of response to specific symptoms. As recommended by the International Spine Intervention Society (ISIS) guidelines, the examiner should identify three or four measurable physical functions, which are currently impaired and can be objectively reassessed 30 minutes or more after the injection. A successful block requires documentation of positive functional changes by trained medical personnel experienced in measuring range of motion or assessing activity performance. The evaluator should be acquainted with the patient, in order to determine pre and post values, and preferably unaffiliated with the injectionist's office. Qualified evaluators include nurses, physician assistants, medical assistants, therapists, or non-injectionist physicians. To be successful the results should occur within the expected timeframe and there should be pain relief of approximately 80% demonstrated by pre and post Visual Analog Scale (VAS) scores. Examples of functional changes may include sitting, walking and lifting. Additionally, a prospective patient completed pain diary must be recorded as part of the medical record that documents response hourly for a minimum requirement of the first 8 hours post injection or until the block has clearly worn off and preferably for the week following an injection. The diary results should be compared to the expected duration of the local anesthetic phase of the procedure. Responses must be identified as to specific body part (e.g., low back, leg pain). The practitioner must identify the local anesthetic used and the expected duration of response for diagnostic purposes.

Multiple injections provided at the same session without staging may seriously dilute the diagnostic value of these procedures and should generally not be performed. Practitioners should carefully weigh the diagnostic value of the procedure against the possible therapeutic value of anticipated treatment changes.

Special Requirements for Spinal Diagnostic Injections

Since multi-planar fluoroscopy during procedures is required to document technique and needle placement**,** an experienced physician should perform the procedure. Injection of contrast dye to assure correct needle placement is required to verify the flow of medication. Permanent images are required to verify needle placement. Unnecessary fluoroscopy procedures should be avoided due to the radiation exposure contributing to cancer risk.

The subspecialty disciplines of the physicians performing the injections may be varied, including, but not limited to: anesthesiology, radiology, surgery, or physiatry. The practitioner should document hands-on training through workshops of the type offered by organizations such as the International Spine Intervention Society (ISIS) with post course proctoring and/or fellowship training with interventional training. They must also be knowledgeable in radiation safety and credentialed by a hospital or surgery center.

Complications

General complications of diagnostic injections may include transient neurapraxia, nerve injury, infection, headache, urinary retention, and vasovagal effects, as well as epidural hematoma, permanent neurologic damage, dural perforation and CSF leakage, and spinal meningeal abscess. There are reports of direct spinal cord injury due to needle trauma. Permanent paresis, anaphylaxis, arachnoiditis, and death have been rarely reported with the use of epidural steroids.

With steroid injections, there may be a dose-dependent suppression of the hypothalamic-pituitary-adrenal axis lasting between one and three months. Case reports of Cushing Syndrome, hypopituitarism and growth hormone deficiency have been tied to systemic absorption of intra-articular and epidural steroid injections.

Cushing's syndrome has been reported from serial occipital nerve injections and paraspinal injections. Several cases of spinal epidural lipomatosis have also been reported that may have been caused or exacerbated by spinal steroid injections.

Morning cortisol measurements may be ordered prior to repeat steroid injections or initial spinal steroid injection when the patient has received multiple previous steroid joint injections.

A well-controlled, large retrospective cohort study found that individuals with the same risk factors for osteoporotic fractures were 20% more likely to suffer a lumbar fracture if they had an epidural steroid injection. The risk increased with multiple injections. Thus the risk of epidural injections must be carefully discussed with the patient, particularly for patients over 60, and repeat injections should generally be avoided unless the functional goals to be reached outweigh the risk for future fracture. Patients with existing osteoporosis or other risk factors for osteoporosis should rarely receive epidural steroid injections.

Contraindications

Absolute contraindications to diagnostic injections include: (a) bacterial infection – systemic or localized to region of injection, (b) bleeding diatheses, (c) hematological conditions, and (d) pain of 3 points or less on a 10-point VAS measurement, e) possible pregnancy, and f) poorly controlled diabetes mellitus for steroid injections.

Relative contraindications to diagnostic injections may include: allergy to contrast, somatization disorders, poorly controlled congestive heart failure (CHF) for steroid injections, risk factors for osteoporosis and uncontrolled hypertension.

Drugs affecting coagulation frequently require restriction from use.

Specific Diagnostic Injections

In general, relief should last for at least the duration of the local anesthetic used and should significantly result in functional improvement and relief of pain. Refer to F.3. Injections – Spinal Therapeutic for information on specific therapeutic injections.

E.2.b.i Epidural Injections

Epidural injections may include caudal, transforaminal, or interlaminar injections. Transforaminal injections are generally accepted and useful in identifying the level of nerve root irritation. When performed for diagnosis, the volume of local anesthetic needed to adequately block the nerve can be estimated by the real time assessment of contrast flow patterns around the nerve prior to the application of local anesthetic. The amount of local anesthetic needed to anesthetize the nerve will generally not be more than 1.0cc.

Needle Placement

Multi-planar fluoroscopic imaging is required for all epidural steroid injections. Injection of contrast dye to assure correct needle placement is required to verify the flow of medication. Permanent images are required to verify needle placement.

Indications

There is strong evidence that epidural injections do not improve long-term outcomes for populations of patients who were diagnosed as having lumbar radicular pain. There is some evidence they may decrease the need for surgery among candidates for nerve decompression and discectomy. In addition, patients can suffer long-term morbidity from injections, although these complications are rare. Therefore, injections are allowed for only a small subset of patients with radicular findings. They may be used for patients who are having significant pain that is interfering with daily functions and the active therapy necessary for recovery despite medical pain management and active therapy. All injections should be preceded by an MRI or a CT scan.

The following sets of patients may have epidural injections:

- When a patient with radicular findings due to herniated disc, meets all of the indications for surgery at approximately 6-8 weeks post active therapy, one epidural may be attempted at the patient's discretion. There is some evidence that after 6 weeks of conservative therapy for large herniated discs an epidural injection may be attempted as it does not compromise the results of a discectomy at a later date. In this study, the initial results of a discectomy were superior to injections and one half of those receiving injections eventually had surgery.
- For rare, acute ruptured (herniated) disc with clear objective radiculopathy if, after one to two weeks of initial oral analgesic and conservative treatment; the patient:
    - has continued pain interfering with most ADL function; and
    - is unable to tolerate the required movements to participate in therapy; and
    - has pain greater in the leg than in the back, generally of 7 or greater on a VAS scale of 10; and
    - has pain following a correlated radicular dermatome; and
    - there is a herniated disc on the MRI at the level of subjective and objective findings; and
    - has either:
        - dual tension signs of straight leg raising or slump test resulting in radicular symptoms correlating with imaging pathology; and/or

        - one of the following documented, reproducible findings, which correlates with the suspected nerve root impingement:
            - Decreased reflexes, or
            - Radicular sensation deficits, or
            - Motor weakness on testing.
- Spinal Stenosis Patients:
    - Patients with radicular findings: When the patient has documented spinal stenosis, has completed 6-8 weeks of active therapy, has persistent radicular findings and difficulty with some activities, thus meeting criteria for surgical intervention, the patient may have one diagnostic injection. Because stenosis is not likely to change anatomically, unlike herniated discs which recede overtime, and due to the success rate of surgery for this condition in most cases, early surgical consultation is encouraged whenever the patient remains symptomatic after conservative therapy. If the patient does not wish to have a surgical intervention two additional injections may be provided if the original diagnostic intervention was successful per guideline standards.
    - Patients with claudication: The patient has documented spinal stenosis, has completed 6-8 weeks of active therapy, has persistent claudication symptoms and difficulty with some activities, thus meeting criteria for surgical intervention. The patient may have one diagnostic injection. Patients who have any objective neurologic findings should proceed as the above patient with radicular findings for whom an early surgical consultation is recommended. Refer to C.1. There is some evidence that translaminar steroid injections do not increase walking tolerance for those with spinal stenosis compared to local anesthetic. Those who have mild claudication, or moderate or severe claudication and who do not desire surgery, may continue to receive up to 2 additional injections if the original diagnostic intervention was successful per guideline standards.

Informed decision making should also be documented for injections and 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. The purpose of spinal injections, as well as surgery, is to facilitate active therapy by providing short-term relief through reduction of pain. Patients should be encouraged to express their personal goals, outcome expectations and desires from treatment as well as any personal habits or traits that may be impacted by procedures or their possible side effects. All patients must commit to continuing appropriate exercise with functionally directed rehabilitation usually beginning within 7 days, at the injectionist's discretion. Since most patients with these conditions will improve significantly over time, without invasive interventions, patients must be able to make well-informed decisions regarding their treatment. All injections must be accompanied by active therapy.

It is obligatory that sufficient data be accumulated by the examiner performing this procedure such that the diagnostic value of the procedure is evident to other reviewers. This entails documentation of patient response regarding the degree and type of response to specific symptoms. As recommended by the ISIS guidelines, the examiner should identify three or four

measurable physical functions, which are currently impaired and can be objectively reassessed 30 minutes or more after the injection. A successful block requires documentation of positive functional changes by trained medical personnel experienced in measuring range of motion or assessing activity performance. The evaluator should be acquainted with the patient, in order to determine pre and post values, and preferably unaffiliated with the injectionist's office. Qualified evaluators include nurses, physician assistants, medical assistants, therapists or non-injectionist physicians. To be successful the results should occur within the expected timeframe and there should be pain relief of approximately 80% demonstrated by pre and post Visual Analog Scale (VAS) scores. Examples of functional changes may include sitting, walking and lifting. Additionally, a prospective patient completed pain diary must be recorded as part of the medical record that documents response hourly for a minimum requirement of the first 8 hours post injection or until the block has clearly worn off and preferably for the week following an injection. The diary results should be compared to the expected duration of the local anesthetic phase of the procedure. Responses must be identified as to specific body part (e.g., low back, leg pain). The practitioner must identify the local anesthetic used and the expected duration of response for diagnostic purposes.

It is essential that only light sedation be used for diagnostic trials in order to avoid having the sedation interfere with the patient's ability to interpret pain relief from the injection itself. Many patients may not need any medication. For those requiring anxiolytics, short acting agents, such as midazolam, may be used. As with all patients, the pain diary and functional testing post injection must be rigorously adhered to in order to correctly interpret the results of the diagnostic injection.

- Time to produce effect: Local anesthetic, less than 30 minutes.

E.2.b.ii Medial Branch Blocks

Medial Branch Blocks are generally accepted diagnostic injections, used to determine whether a patient is a candidate for radiofrequency medial branch neurotomy (also known as facet rhizotomy).

It is obligatory that sufficient data be accumulated by the examiner performing this procedure such that the diagnostic value of the procedure is evident to other reviewers. This entails documentation of patient response regarding the degree and type of response to specific symptoms. As recommended by the ISIS guidelines, the examiner should identify three or four measurable physical functions, which are currently impaired and can be objectively reassessed 30 minutes or more after the injection. A successful block requires documentation of positive functional changes by trained medical personnel experienced in measuring range of motion or assessing activity performance. The evaluator should be acquainted with the patient, in order to determine pre and post values, and preferably unaffiliated with the injectionist's office. Qualified evaluators include nurses, physician assistants, medical assistants, therapists or non-injectionist physicians. To be successful the results should occur within the expected timeframe and there should be pain relief of approximately 80% demonstrated by pre and post Visual Analog Scale

(VAS) scores. Examples of functional changes may include sitting, walking and lifting. Additionally, a prospective patient completed pain diary must be recorded as part of the medical record that documents response hourly for a minimum requirement of the first 8 hours post injection or until the block has clearly worn off and preferably for the week following an injection. The diary results should be compared to the expected duration of the local anesthetic phase of the procedure. Responses must be identified as to specific body part (e.g., low back, leg pain). The practitioner must identify the local anesthetic used and the expected duration of response for diagnostic purposes. The success rate of radiofrequency neurotomy is likely to decrease with lesser percentages of pain relief from a branch block.

A separate comparative block on a different date should be performed to confirm the level of involvement. A comparative block uses anesthetics of varying lengths of activity. Medial Branch blocks are probably not helpful to determine the likelihood of success for spinal fusion.

It is essential that only light sedation be used for diagnostic trials in order to avoid having the sedation interfere with the patient's ability to interpret pain relief from the injection itself. Many patients may not need any medication. For those requiring anxiolytics, short acting agents, such as midazolam, may be used. As with all patients, the pain diary and functional testing post injection must be rigorously adhered to in order to correctly interpret the results of the diagnostic injection.

Needle Placement
Multi-planar fluoroscopic imaging is required for all medial branch blocks injections. Injection of contrast dye to assure correct needle placement is required to verify the flow of medication. Permanent images are required to verify needle placement.

Indications
All injections should be preceded by an MRI or a CT scan. Individuals should have met all of the following indications:

- Physical exam findings consistent with facet origin pain, and
- At least 3 months of pain, unresponsive to 6-8 weeks of conservative therapies, including manual therapy, and
- A psychosocial screening (e.g., thorough psychosocial history, screening questionnaire) with treatment as appropriate.

- Frequency and Maximum Duration: May be repeated once for comparative blocks. Limited to 2 anatomic facet levels or 3 medial branch levels.

E.2.b.iii Sacroiliac Joint Injections

Description
A generally accepted injection of local anesthetic in an intra-articular fashion into the sacroiliac joint under fluoroscopic guidance. Long-term therapeutic effect has not yet been established.

Needle Placement

Multi-planar fluoroscopic imaging is required for all steroid injections. Injection of contrast dye to assure correct needle placement is required to verify the flow of medication. Permanent images are required to verify needle placement.

Indications

Primarily diagnostic to rule out sacroiliac joint dysfunction versus other pain generators. Intra-articular injection can be of value in diagnosing the pain generator. To qualify for an injection the patient must have at least 3 positive physical exam maneuvers (e.g. Patrick's sign, Faber's test, Ganslen, distraction or gapping, or compression test).

It is obligatory that sufficient data be accumulated by the examiner performing this procedure such that the diagnostic value of the procedure is evident to other reviewers. This entails documentation of patient response regarding the degree and type of response to specific symptoms. The examiner should identify three or four measurable provocative physical exam maneuvers (e.g. Patrick's sign, Faber's test, Gaenslen, distraction or gapping, or compression test), and physical functions, which are currently impaired and can be objectively reassessed 30 minutes or more after the injection. A successful block requires documentation of positive functional changes by trained medical personnel experienced in measuring range of motion or assessing activity performance. The evaluator should be acquainted with the patient, in order to determine pre and post values, and preferably unaffiliated with the injectionist's office. Qualified evaluators include nurses, physician assistants, medical assistants, therapists, or non-injectionist physicians. To be successful the results should occur within the expected timeframe and there should be pain relief of approximately 80% demonstrated by pre and post Visual Analog Scale (VAS) scores. Examples of functional changes may include sitting, walking, and lifting. Additionally, a prospective patient completed pain diary must be recorded as part of the medical record that documents response hourly for a minimum requirement of the first 8 hours post injection or until the block has clearly worn off and preferably for the week following an injection. The diary results should be compared to the expected duration of the local anesthetic phase of the procedure. Responses must be identified as to specific body part (e.g., low back, leg pain). The practitioner must identify the local anesthetic used and the expected duration of response for diagnostic purposes.

It is essential that only light sedation be used for diagnostic trials in order to avoid having the sedation interfere with the patient's ability to interpret pain relief from the injection itself. Many patients may not need any medication. For those requiring anxiolytics, short acting agents, such as midazolam, may be used. As with all patients, the pain diary and functional testing post injection must be rigorously adhered to in order to correctly interpret the results of the diagnostic injection.

Responses must be identified as to specific body part (e.g., low back, leg pain). The practitioner must identify the local anesthetic used and the expected duration of response for diagnostic purposes. Sacroiliac joint blocks should facilitate functionally directed rehabilitation programs or

may be done to determine the need for radiofrequency SI procedure. All injections should be preceded by an MRI or a CT scan.

- Time to Produce Effect: Up to 30 minutes for local anesthetic.
- Frequency and Maximum Duration: 1 injection. It is recommended that morning cortisol levels are checked prior to the 3rd or 4th steroid injection.

E.2.b.iv Zygapophyseal (Facet) Blocks

Description
An accepted intra-articular or pericapsular injection of local anesthetic and corticosteroid with very limited uses. There is no justification for a combined facet and medial branch block.

These injections have not been proven to change the long-term course of most patients with spinal pain. They have a limited role in treatment and should be used in only a small subset of patients where the criteria below have been clearly met. Refer to F.3. Injections –Spinal Therapeutic, for indications.

Needle Placement
Injection of contrast dye to assure correct needle placement is required to verify the flow of medication. Permanent images are required to verify needle placement.

Indications
Patients with pain 1) suspected to be facet in origin based on exam findings and 2) affecting activity; OR patients who have refused a rhizotomy and appear clinically to have facet pain; OR patients who have facet findings with a thoracic component. The physician should document the findings which, for lumbar and cervical spine, consist of pain with extension and lateral bending with referral patterns consistent with the expected pathologic level. In these patients, facet injections may be occasionally useful in facilitating a functionally-directed rehabilitation program and to aid in identifying pain generators. Patients with recurrent pain should be evaluated with more definitive diagnostic injections, such as medial nerve branch injections, to determine the need for a rhizotomy. Because facet injections are not likely to produce long-term benefit by themselves and are not the most accurate diagnostic tool, they should not be performed at more than two levels, neither unilaterally nor bilaterally. A high quality meta-analysis provides good evidence against the use of lumbar facet or epidural injections for relief of non-radicular low back pain. Due to the lack of proof that these injections improve outcome, prior authorization is required. All injections should be preceded by an MRI or a CT scan.

Informed decision making should also be documented for injections and 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. The purpose of spinal injections is to facilitate active therapy by providing short-term relief through reduction of pain. Patients should be encouraged to express their personal goals, outcome expectations and desires from treatment as well as any personal habits or traits that may be impacted by procedures or

their possible side effects. Patients should be encouraged to express their personal goals, outcome expectations and desires from treatment as well as any personal habits or traits that may be impacted by procedures or their possible side effects. All patients must commit to continuing appropriate exercise with functionally directed rehabilitation, usually beginning within 7 days, at the injectionist's discretion. Since most patients with these conditions will improve significantly over time, without invasive interventions, patients must be able to make well-informed decisions regarding their treatment. All injections must be accompanied by active therapy.

It is obligatory that sufficient data be accumulated by the examiner performing this procedure such that the diagnostic value of the procedure is evident to other reviewers. This entails documentation of patient response regarding the degree and type of response to specific symptoms. As recommended by the ISIS guidelines, the examiner should identify three or four measurable physical functions, which are currently impaired and can be objectively reassessed 30 minutes or more after the injection. A successful block requires documentation of positive functional changes by trained medical personnel experienced in measuring range of motion or assessing activity performance. The evaluator should be acquainted with the patient, in order to determine pre and post values, and preferably unaffiliated with the injectionist's office. Qualified evaluators include nurses, physician assistants, medical assistants, therapists, or non-injectionist physicians. To be successful the results should occur within the expected timeframe and there should be pain relief of approximately 80% demonstrated by pre and post Visual Analog Scale (VAS) scores. Examples of functional changes may include sitting, walking, and lifting. Additionally, a prospective patient completed pain diary must be recorded as part of the medical record that documents response hourly for a minimum requirement of the first 8 hours post injection or until the block has clearly worn off and preferably for the week following an injection. The diary results should be compared to the expected duration of the local anesthetic phase of the procedure. Responses must be identified as to specific body part (e.g., low back, leg pain). The practitioner must identify the local anesthetic used and the expected duration of response for diagnostic purposes.

It is essential that only light sedation be used for diagnostic trials in order to avoid having the sedation interfere with the patient's ability to interpret pain relief from the injection itself. Many patients may not need any medication. For those requiring anxiolytics, short acting agents, such as midazolam, may be used. As with all patients, the pain diary and functional testing post injection must be rigorously adhered to in order to correctly interpret the results of the diagnostic injection.

- Time to produce effect: Up to 30 minutes for local anesthetic.
- Frequency and Maximum Duration: Once per suspected level, limited to two levels unilaterally or bilaterally. If radiofrequency neurotomy is being considered, refer to the medial branch block section. It is recommended that morning cortisol levels are checked prior to the 3rd or 4th steroid injection.

E.2.c Personality/Psychological/Psychosocial Evaluation

Personality/Psychological/Psychosocial Evaluation consists of generally accepted and well-established diagnostic procedures with selective use in the acute low back pain populations and more widespread use in sub-acute and chronic low back pain populations.

These diagnostic testing procedures may be useful for patients with symptoms of depression, delayed recovery, chronic pain, recurrent painful conditions, disability problems, and for pre-operative evaluation, as well as having a possible predictive value for post-operative response. Psychological testing should provide differentiation between pre-existing depression versus injury-caused depression, as well as post-traumatic stress disorder.

There is some evidence that depression is a more accurate predictor of the development of low back pain than many common MRI findings, such as disc bulges, disc protrusions, Modic endplate changes, disc height loss, annular tears, and facet degeneration, which are common in asymptomatic persons and are not associated with the development of low back pain.

Psychosocial evaluations should determiine if further psychosocial interventions are indicated for patients diagnosed with chronic pain. The interpretations of the evaluation should provide clinicians with a better understanding of the patient in his or her social environment, thus allowing for more effective rehabilitation. Psychosocial assessment requires consideration of variations in pain experience and expression resulting from affective, cognitive, motivational and coping processes, and other influences such as gender, age, race, ethnicity, national origin, religion, sexual orientation, disability, language, or socioeconomic status.

While there is some agreement about which psychological factors need to be assessed in patients with chronic pain, a comprehensive psychological evaluation should attempt to identify both primary psychiatric risk factors or “red flags” (e.g. psychosis, active suicidality), as well as secondary risk factors or “yellow flags” (e.g. moderate depression, job dissatisfaction). Significant personality disorders must be taken into account when considering a patient for spinal cord stimulation and other major procedures.

Psychometric Testing is a valuable component of a consultation to assist the physician in making a more effective treatment plan. There is good evidence that psychometric testing can have significant ability to predict medical treatment outcome. For example, one study found that psychometric testing exceeded the ability of discography to predict disability in patients with low back pain. Pre-procedure psychiatric/psychological evaluation must be done prior to diagnostic confirmatory testing for the procedure. Examples include discography for fusion, spinal cord stimulation, or intrathecal drug delivery systems and should not be done by a psychologist employed by the physician planning to perform the procedure.

In many instances, psychological testing has validity comparable to that of commonly used medical tests; for example, the correlation between high trait anger and blood pressure is equal to the correlation between reduced blood flow and the failure of a synthetic hemodialysis graft.

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Thus, psychometric testing may be of comparable validity to medical tests and may provide unique and useful diagnostic information.

Psychological tests must include validity scales which provide data on the veracity of psychiatric, cognitive and physical reports of symptoms. Tests with clinical scales that provide data on levels of anxiety, somatization and depression are most useful in making reliable determinations with regard to the patient's psychological status. The MMPI- Restructured Form or alternately the MMPI-2, share an extensive research base with regard to the validity of symptom reporting and are recommend for standard of care assessments in pain populations.

Formal psychological or psychosocial evaluation should be performed on patients not making expected progress within 6–12 weeks following injury and whose subjective symptoms do not correlate with objective signs and tests. In addition to the customary initial exam, the evaluation of the injured worker should specifically address the following areas:

- Employment history;
- Interpersonal relationships, both social and work;
- Leisure activities;
- Current perception of the medical system;
- Results of current treatment;
- Perceived locus of control; and
- Childhood history, including abuse and family history of disability.

This information should provide clinicians with a better understanding of the patient and enable a more effective rehabilitation. The evaluation will determine the need for further psychosocial interventions, and in those cases, a Diagnostic Statistical Manual of Mental Disorders (DSM) diagnosis should be determined and documented. An individual with a PhD, PsyD, or Psychiatric MD/DO credentials should perform initial evaluations, which are generally completed within one to two hours. A professional fluent in the primary language of the patient is strongly preferred. When such a provider is not available, services of a professional language interpreter must be provided. When issues of chronic pain are identified, the evaluation should be more extensive and follow testing procedures as outlined in the Department's Chronic Pain Disorder Guideline.

- Frequency: One time visit for evaluation. If psychometric testing is indicated as a portion of the initial evaluation, time for such testing should not exceed an additional two hours of professional time. Evaluation and testing are billed separately.

E.2.d Provocation Discography

Description

Discography is accepted, but rarely indicated. It remains extremely controversial as an invasive diagnostic procedure to identify or refute a discogenic source of pain for patients who are surgical candidates for fusion or disc replacement. Discography should only be performed by physicians who are experienced and have been proctored in the technique. Discograms have a

significant false positive rate. It is essential that all indications, pre-conditions, special considerations, procedures, reporting requirements and results are carefully and specifically followed. Results should be interpreted judiciously.

Indications

Discography may be indicated when a patient has a history of functionally limiting, unremitting low back pain of greater than four months duration, with or without leg pain, which has been unresponsive to all conservative interventions and meets all of the criteria for spinal fusion. A patient who does not desire operative therapeutic intervention is not a candidate for an invasive non-therapeutic intervention, such as provocation discography. When a patient exhibits pain with extension and lateral bending of the spine, facet pathology should be explored prior to a discogram.

Discography may prove useful in evaluating the number of lumbar spine levels that might require fusion. Discography provides further detailed information about morphological abnormalities of the disc and possible lateral disc herniations.

Discography may indicate disc degeneration and annular disruption in the absence of low back pain. Discography may also elicit concordant pain in patients with mild and functionally inconsequential back pain. Because patients with mild back pain (3 points or less on a 10-point VAS measurement should not be considered for invasive treatment) discography should not be performed on these patients. In symptomatic patients with annular tears, the side of the tear does not necessarily correlate with the side on which the symptoms occur. The presence of an annular tear does not necessarily identify the tear as the pain generator.

There is good evidence that a positive discogram does not predict positive results from a fusion with the same success rate as documented spondylolisthesis (27% success rate compared to 72% success rate). A similar prospective study found that a painful disc (that is, a positive discogram) is a poor independent predictor of low back pain in initially asymptomatic subjects. Psychometric profiles, work loss, medication usage were strongly predictive of subsequent low back pain. An annular tear of high intensity zone on MRI was weakly associated.

There is some evidence that discography with a small-bore needle increases the risk of later disc herniation at the injected level, and this risk should be taken into account when deciding on a referral for discography.

Pre-conditions for provocation discography include all of the following.

1. A patient with functionally limiting, unremitting back and/or leg pain of greater than four months duration in whom conservative treatment has been unsuccessful and in whom the specific diagnosis of the pain generator has not been made apparent on the basis of other non-invasive imaging studies (e.g., MRI, CT, plain films, etc.). It is recommended that discography be reserved for use in patients with equivocal MRI findings, especially at levels adjacent to clearly pathological levels. Discography may be more sensitive than

MRI or CT in detecting radial annular tears. However, radial tears must always be correlated with clinical presentation.

2. Prior to consideration of discography, the patient should undergo other diagnostic testing as appropriate in an effort to define the etiology of the patient's complaint including psychological evaluation, myelography, CT, and MRI.

3. Psychosocial evaluation has been completed. There is some evidence that discography in patients with somatoform disorders is likely to create a risk of development of persistent low back pain in the year following the procedure. Therefore, discograms should not be performed on patients with somatoform disorders.

4. Patients are considered surgical candidates (e.g., symptoms are of sufficient magnitude and the patient has been informed of the possible surgical and non-surgical options that may be available based upon the results of discography). Informed decision making should always be documented. Discography should never be the sole indication for surgery.

5. Informed consent regarding the risks and potential diagnostic benefits of discography has been obtained.

Complications
Include, but are not limited to, discitis, nerve damage, chemical meningitis, pain exacerbation, possible damage to the control disc being injected and anaphylaxis.

There is some evidence that discography with a small-bore needle increases the risk of later disc herniation at the injected level and this risk should be taken into account when deciding on a referral for discography.

Contraindications
Include: (a) active infection of any type or continuing antibiotic treatment for infection; (b) bleeding diathesis or pharmaceutical anticoagulation with warfarin, etc.; (c) significant spinal stenosis at the level being studied as visualized by MRI, myelography or CT scan; (d) presence of clinical myelopathy; (e) effacement of the cord, thecal sac or circumferential absence of epidural fat; and/or (f) known allergic reactions.

Special Considerations
Discography should not be performed by the physician expected to perform the therapeutic procedure nor by physicians in the same practice. The procedure should be carried out by an experienced individual who has received specialized training in the technique of provocation discography.

Discography should be performed in a blinded format that avoids leading the patient with anticipated responses. The procedure should always include one or more disc levels thought to be normal or non-painful in order to serve as an internal control. The patient should not know

what level is being injected in order to avoid spurious results. An injection may be repeated on abnormal disc levels to confirm concordance.

Sterile technique must be utilized.

It is essential that only light sedation be used for diagnostic trials in order to avoid having the sedation interfere with the patient's ability to interpret pain relief from the injection itself. Many patients may not need any medication. For those requiring anxiolytics, short acting agents, such as midazolam, may be used. As with all patients, the pain diary and functional testing post injection must be rigorously adhered to in order to correctly interpret the results of the diagnostic injection.

The discography should be performed using a manometer to record pressure. The injection may continue until either: pain is produced; contrast medium escapes from the disc; the volume of injection reaches 3mL; or a maximum pressure range of 50-75 per square inch (psi) over opening pressure is reached.

Intradiscal injection of local anesthetic may be carried out after the provocation portion of the examination and the patient's response.

A post-discogram CT may be considered as it frequently provides additional useful information about disc morphology or other pathology, however it also increases radiation exposure.

Reporting of Discography

In addition to a narrative report, the discography report should contain a standardized classification of (a) disc morphology (b) the pain response, and (c) the pressure at which pain is produced. All results should be clearly separated in the report from the narrative portion. Asymptomatic annular tears are common. The concordant pain response is an essential finding for a positive discogram.

When discography is performed to identify the source of a patient's low-back pain, both a concordant pain response and morphological abnormalities must be present at the pathological level prior to initiating any treatment directed at that level. The patient must be awake during the provocation phase of the procedure; therefore, sedative medication must be carefully titrated.

Caution should be used when interpreting results from discography. Several studies indicate that a false positive discogram for pain is likely above a pressure reading of 50 psi above opening pressure. When the psi associated with concordant pain is 20 psi or less from the opening pressure, the false positive rate drops to approximately 25%.

Reporting disc morphology as visualized by the post-injection CT scan (when available) should follow the Modified Dallas Discogram Scale where:

Grade 0 = Normal Nucleus.

Grade 1 = Annular tear confined to inner one-third of annulus fibrosis.

Grade 2 = Annular tear extending to the middle third of the annulus fibrosis.

Grade 3 = Annular tear extending to the outer one-third of the annulus fibrosis.

Grade 4 = A grade 3 tear plus dissection within the outer annulus to involve more than 30° of the disc circumference.

Grade 5 = Full thickness tear with extra-annular leakage of contrast, either focal or diffuse.

Reporting the pain response should be consistent with the operational criteria of the International Spine Intervention Society (ISIS) Guidelines. The report must include the level of concordance for back pain and leg pain separately using a 10-point VAS, or similar quantitative assessment. It should be noted that change in the VAS scale before and after provocation is more important than the number reported. The definition of a positive discogram is noted below. Two control discs are no longer routinely recommended due to the possibility that a disc injection alone may cause later pathology.

Positive discogram:

- Stimulation of the target disc reproduces concordant pain; and
- The pain is registered as at least 7 on a 10-point VAS; and has increased significantly from the baseline value; and
- The pain is reproduced at a pressure of less than 50 psi above opening pressure; and
- Stimulation of at least one adjacent disc does not produce pain at all.

If the patient does not qualify using the criteria above, then the discogram should be considered negative. The VAS score prior to the discogram should be taken into account when interpreting the VAS score reported by the patient during the discogram.

Time parameters for provocation discography are as follows:

- Frequency: One time only.
- Maximum Duration: Repeat Discography is rarely indicated.

E.2.e Thermography

Thermography is an accepted and established procedure, but it has no use as a diagnostic test for low back pain. It may be used to diagnose complex regional pain disorders. Refer to the Department's Complex Regional Pain Syndrome Guideline.

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E.3 Special Tests

Special Tests are generally well-accepted tests and are performed as part of a skilled assessment of the patients' capacity to return to work, his/her strength capacities and physical work demand classifications and tolerance. The procedures in this subsection are listed in alphabetical order, not by importance.

E.3.a Computer-Enhanced Evaluations

Computer-Enhanced Evaluations may include isotonic, isometric, isokinetic and/or isoinertial measurement of movement; range of motion (ROM); endurance; or strength. Values obtained can include degrees of motion, torque forces, pressure or resistance. Indications include determining validity of effort, effectiveness of treatment, and demonstrated motivation. These evaluations should not be used alone to determine return to work restrictions.

- Frequency: One time for evaluation, one for mid-treatment assessment, and one at final evaluation.

E.3.b Functional Capacity Evaluation (FCE)

Functional Capacity Evaluation (FCE) is a comprehensive or modified evaluation of the various aspects of function as they relate to the worker's ability to return to work. Areas such as endurance, lifting (dynamic and static), postural tolerance, specific range of motion (ROM), coordination and strength, worker habits, employability, as well as psychosocial aspects of competitive employment may be evaluated. Reliability of patient reports and overall effort during testing is also reported. Components of this evaluation may include: (a) musculoskeletal screen; (b) cardiovascular profile/aerobic capacity; (c) coordination; (d) lift/carrying analysis; (e) job-specific activity tolerance; (f) maximum voluntary effort; (g) pain assessment/psychological screening; and (h) non-material and material handling activities. Standardized national guidelines (such as National Institute for Occupational Safety and Health (NIOSH)) should be used as the basis for FCE recommendations.

There is some evidence that an FCE fails to predict which injured workers with chronic low back pain will have sustained return to work. Another cohort study concluded that there was a significant relation between FCE information and return to work, but the predictive efficiency was poor. There is some evidence that time off work and gender are important predictors for return to work, and floor-to-waist lifting may also help predict return to work, however, the strength of that relationship has not been determined.

A full review of the literature reveals that there is no evidence to support the use of FCEs to prevent future injuries. There is some evidence in chronic low back pain patients that (1) FCE task performance is weakly related to time on disability and time for claim closure and (2) even claimants who fail on numerous physical performance FCE tasks may be able to return to work.

Full FCEs may not be necessary. In many cases, a work tolerance screening or return to work

performance will identify the ability to perform the necessary job tasks. There is some evidence that a short form FCE reduced to a few tests produces a similar predictive quality compared to the longer 2-day version of the FCE regarding length of disability and recurrence of a claim after return to work.

When an FCE is being used to determine return to a specific jobsite, the provider is responsible for fully understanding the physical demands and the duties of the job the worker is attempting to perform. A jobsite evaluation is usually necessary. A job description should be reviewed by the provider and FCE evaluator prior to having this evaluation performed. FCEs cannot be used in isolation to determine work restrictions. It is expected that the FCE may differ from both self-report of abilities and pure clinical exam findings in chronic low back pain patients. The length of a return to work evaluation should be based on the judgment of the referring physician and the provider performing the evaluation. Since return to work is a complicated multidimensional issue, multiple factors beyond functional ability and work demands should be considered and measured when attempting determination of readiness or fitness to return to work. FCEs should not be used as the sole criteria to diagnose malingering.

- Frequency: Can be used: (1) initially to determine baseline status; and (2) for case closure when patient is unable to return to the pre-injury position and further information is desired to determine permanent work restrictions. Prior authorization is required for FCEs performed during treatment.

E.3.c Jobsite Evaluation

Jobsite Evaluation is a comprehensive analysis of the physical, mental, and sensory components of a specific job. These components may include, but are not limited to: (a) postural tolerance (static and dynamic); (b) aerobic requirements; (c) ROM; (d) torque/force; (e) lifting/carrying; (f) cognitive demands; (g) social interactions; (h) visual perception; (i) sensation; (j) coordination; (k) environmental factors; (l) repetitiveness; and (m) essential job functions.

Job descriptions and/or job analyses provided by the employer are helpful but should not be used as a substitute for direct observation or job analysis.

A jobsite evaluation may include observation and instruction of how work is done, what material changes (desk, chair) should be made, and determination of readiness to return to work.

Requests for a jobsite evaluation should describe the expected goals for the evaluation. Goals may include, but are not limited to the following:

- To determine if there are potential contributing factors to the person's condition and/or for the physician to assess causality;
- To make recommendations for, and to assess the potential for ergonomic changes;
- To provide a detailed description of the physical and cognitive job requirements;
- To assist the patient in their return to work by educating them on how they may be able to do their job more safely in a bio-mechanically appropriate manner;
- To give detailed work/activity restrictions.

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Frequency: One time with 1-2 additional visits as needed for follow-up per jobsite.

E.3.d Vocational Assessment

If the injury is such that the practitioner can easily determine that the worker will be unable to return to his/her previous occupation, then vocational assessment at that time may aid in the overall medical management and rehabilitation of the patient. The physician may decide that the patient is unable to return to the previous occupation prior to declaration of maximum medical improvement (MMI).

The vocational assessment should provide valuable guidance in the determination of future rehabilitation program goals. It should clarify rehabilitation goals, which optimize both patient motivation and utilization of rehabilitation resources. The physician should have identified the expected permanent limitation(s) prior to the assessment. Declaration of MMI should not be delayed solely due to lack of attainment of a vocational assessment.

- Frequency: One time with additional visits as needed for follow-up.

E.3.e Work Tolerance Screening

Work Tolerance Screening is a determination of an individual's tolerance for performing a specific job as based on a job activity or task and is generally preferable to a full FCE. It may include a test or procedure to specifically identify and quantify work-relevant cardiovascular fitness, physical fitness, and postural tolerance. It may also address ergonomic issues affecting the patient’s return to work potential.

- Frequency: One time for initial screen. May monitor improvements in strength every 3 to 4 weeks up to a total of 6 visits.

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F. 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 or restricted duty during their rehabilitation at the earliest appropriate time. Refer to F.11 Return to Work 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. 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 the patient's 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.

F.1 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.

There is good evidence that acupuncture, true or sham, is superior to usual care for the reduction of disability and pain in patients with chronic nonspecific low back pain, and that true and sham acupuncture are likely to be equally effective. A sham procedure is a non-therapeutic procedure

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that appears similar to the patient as the purported therapeutic procedure being tested. In most controlled studies, sham and classic acupuncture have produced similar effects. However, the sham controlled studies have shown consistent advantages of both true and sham acupuncture over no acupuncture when the studies have included a third comparison group that was randomized to usual medical care. Having this third comparison group has been advantageous in the interpretation of the non-specific effects of acupuncture, since the third comparison group controls for some influences on study outcome. These influences include more frequent contact with providers, the natural history of the condition, regression to the mean, the effect of being observed in a clinical trial, and, if the follow-up observations are done consistently in all three treatment groups, for biased reporting of outcomes. Controlling for these factors enables researchers to more closely estimate the contextual and personal interactive effects of acupuncture as it is generally practiced.

Because the sham acupuncture interventions in the clinical trials are generally done by trained acupuncturists, and not by totally untrained personnel, the sham acupuncture interventions may include some of the effects of true acupuncture, much as a partial agonist of a drug may produce some of the effects of the actual drug. For example, a sham procedure involving toothpicks rather than acupuncture needles may stimulate cutaneous afferents in spite of not penetrating the skin, much as a neurological sensory examination may test nociceptor function without skin penetration. To the extent that afferent stimulation is part of the mechanism of action of acupuncture, interpreting the sham results as purely a control group would lead to an underestimation of the analgesic effects of acupuncture. Thus we consider in our analysis that "sham" or non-classic acupuncture may have a positive clinical effect when compared to usual care.

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 would be expected of 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.

There is good evidence there is a likely, small clinical benefit of acupuncture for acute low back pain and it may be considered an alternative for some patients. There is good evidence that both acupuncture and sham acupuncture are superior to usual care without acupuncture for moderate short-term and mild long-term alleviation of low back pain, neck pain, and the pain of joint osteoarthritis. Another study provides good evidence that true acupuncture at traditional medians is marginally better than sham acupuncture with blunt needles in reducing pain, but effects on disability are unclear. In these studies 5–15 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.

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 low back pain for patients who cannot tolerate nonsteroidal 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 F.4.h. Trigger Point Injections and Dry Needling Treatment.

Credentialed practitioners with experience in evaluation and treatment of chronic pain patients must perform acupuncture evaluations. The exact mode of action is only partially understood. Western medicine studies suggest that acupuncture stimulates the nervous system at the level of the brain, promotes deep relaxation, and affects the release of neurotransmitters. Acupuncture is commonly used as an alternative or in addition to traditional Western pharmaceuticals. It may be used when pain medication is reduced or not tolerated; as an adjunct to physical rehabilitation and surgical intervention; and/or as part of multidisciplinary treatment to hasten the return of functional activity. Acupuncture must be performed by practitioners with the appropriate credentials in accordance with state and other applicable regulations. Therefore, if not otherwise within their professional scope of practice and licensure, those performing acupuncture must have the appropriate credentials, such as L.A.c., R.A.c, or Dipl. Ac.

F.1.a 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 has a variety of possible physiologic actions, but their relevance to the clinical response is speculative. For example, one crossover trial measured increasing palmar blood flow and increased nitric oxide synthase activity in arms which had had acupuncture, but this observation may have no bearing on actual analgesic effects.

Indications include joint pain, joint stiffness, soft tissue pain and inflammation, paresthesia, post-surgical pain relief, muscle spasm, and scar tissue pain.

F.1.b Acupuncture with Electrical Stimulation

Acupuncture with Electrical Stimulation is the use of electrical current (micro-amperage or milli-amperage) 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.

F.1.c 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 F.12.g. Therapeutic Exercise, F.13.g. Massage – Manual or Mechanical, and F.13.k. Superficial Heat and Cold Therapy

(excluding Infrared Therapy) for a description of these adjunctive acupuncture modalities and timeframes.

F.1.d Timeframes for Acupuncture and Acupuncture with Electrical Stimulation

Timeframes are not meant to be applied to each of the above sections separately. The timeframes are to be applied to all acupuncture treatments regardless of the type or combination of therapies being provided.

- Time to produce effect: 3 to 6 treatments
- Frequency: 1 to 3 times per week
- Optimum duration: 1 to 2 months
- Maximum duration: 15 treatments

Any of the above 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 15 treatments must be documented with respect to need and the ability to facilitate positive symptomatic and functional gains. Such care should be re-evaluated and documented with each series of treatments. All treatments should be accompanied by active therapy.

F.2 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 psycho-physiological 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, auditorily, 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.

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.

Recognized types of biofeedback include the following:

- Electromyogram (EMG): Used for self-management of pain and stress reactions involving muscle tension.

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- Skin Temperature: Used for self-management of pain and stress reactions, especially vascular headaches.
- Respiration Feedback (RFB): Used for self-management of pain and stress reactions via breathing control.
- Respiratory Sinus Arrhythmia (RSA): Used for self-management of pain and stress reactions via synchronous control of heart rate and respiration. Respiratory sinus arrhythmia is a benign phenomenon that consists of a small rise in heart rate during inhalation, and a corresponding decrease during exhalation. This phenomenon has been observed in meditators and athletes, and is thought to be a psycho-physiological indicator of health.
- Heart Rate Variability (HRV): Used for self-management of stress via managing cardiac reactivity.
- Electrodermal Response (EDR): Used for self-management of stress involving palmar sweating or galvanic skin response.
- Electroencephalograph (EEG, QEEG): Used for self-management of various psychological states by controlling brainwaves.

The goal in biofeedback treatment is normalizing the physiology to the pre-injury status to the extent possible and involves transfer of learned skills to the workplace and daily life. Candidates for biofeedback therapy or training should be motivated to learn and practice biofeedback and self-regulation techniques. In the course of biofeedback treatment, patient stressors are discussed and self-management strategies are devised. If the patient has not been previously evaluated, a psychological evaluation should be performed prior to beginning biofeedback treatment for chronic pain. The psychological evaluation may reveal cognitive difficulties, belief system conflicts, somatic delusions, secondary gain issues, hypochondriasis, and possible biases in patient self-reports, which can affect biofeedback. Home practice of skills is often helpful for mastery and may be facilitated by the use of home training tapes.

Psychologists or psychiatrists who provide psycho-physiological therapy, which integrates biofeedback with psychotherapy, should be either Biofeedback Certification International Alliance (BCIA) certified or practicing within the scope of their training and licensure. All non-licensed health care providers of biofeedback for chronic pain patients must be BCIA certified and shall have their biofeedback treatment plan approved by the authorized treating psychologist or psychiatrist. Biofeedback treatment must be done in conjunction with the patient's psychosocial intervention. Biofeedback may also be provided by health care providers who follow a set treatment and educational protocol. Such treatment may utilize standardized material or relaxation tapes.

- Time to produce effect: 3 to 4 sessions
- Frequency: 1 to 2 times per week
- Optimum duration: 6 to 8 sessions

- Maximum duration: 10 to 12 sessions. Treatment beyond 12 sessions must be documented with respect to need, expectation, and ability to facilitate positive functional gains.

F.3 Injections – Spinal Therapeutic

Description

Therapeutic spinal injections are established procedures. Regarding short-term benefits from injections, there is strong evidence that epidural steroid injections have a small average short term benefit for leg pain and disability for those with sciatica. Additionally, specific to transforaminal injections, there is good evidence that the addition of steroids to a transforaminal bupivacaine injection has a small effect on patient reported pain and disability.
Regarding long term benefit from injections, there is strong evidence that epidural steroid injections (ESI) do not, on average , provide clinically meaningful long-term improvements in leg pain, back pain, or disability in patients with sciatica (lumbar radicular pain or radiculopathy).

Conversely, there is some evidence that the addition of steroids to a transforaminal bupivacaine injection may reduce the frequency of surgery in the first year after treatment in patients with neurologic compression and corresponding imaging findings who also are strong candidates for surgery and have completed 6 weeks of therapy without adequate benefit. There is some evidence that the benefits for the non-surgical group persisted for at least 5 years in most patients, regardless of the type of block given. An additional study provides some evidence that after 6 weeks of conservative therapy for large herniated discs, an epidural injection may be attempted, as it does not compromise the results of a discectomy at a later date. One half of the patients in this study who were randomized to ESIs did not have surgery and this benefit persisted. Because this study did not have a control group that received neither treatment, nor a group which received injections without steroids, one cannot make definite conclusions regarding the efficacy of ESI injections in this setting.

There is strong evidence that ESI has no short or long term benefit for low back pain. A high quality meta-analysis provides additional good evidence against the use of lumbar facet or epidural injections for relief of non-radicular low back pain. Facet injections have very limited therapeutic or diagnostic use. Refer to F.3.e. Zygapophyseal (Facet) Injections.

In summary, there is no proven benefit from adding steroids to local anesthetic spinal injections for most injections, with the possible exception of patients who are strong candidates for surgery based on a herniated disc and clear nerve impingement. However, steroids are currently used routinely in spinal injections due to a presumed physiologic effect.

Therapeutic spinal injections have not been proven to change the long-term course of most patients with spinal pain. They have a limited role in treatment and should be used in only a small subset of patients where the criteria below have been clearly met. Refer to the specific injections as described in this section for indications.

Therapeutic injections should only be used after diagnostic injections and imaging studies have established pathology which has not clinically improved after active engagement (6-8 weeks) of physical therapy and in patients who otherwise qualify for more invasive procedures and may need injections because they do not wish to proceed to surgery.

The purpose of spinal injections is to facilitate active therapy by providing short-term relief through reduction of pain and inflammation. All patients must commit to continuing appropriate exercise with functionally directed rehabilitation usually beginning within 7 days, at the injectionist's discretion. Active treatment, which patients should have had prior to injections, will frequently require a repeat of the sessions previously ordered (Refer to F.12. Therapy-Active). Injections, by themselves, are not likely to provide long-term relief. Rather, active rehabilitation with modified work achieves long-term relief by increasing active range of motion (ROM), strength, and stability.

It is obligatory that sufficient data be accumulated by the examiner performing this procedure such that the value of the procedure is evident to other reviewers. This entails documentation of patient response regarding the degree and type of response to specific symptoms. As recommended by the ISIS guidelines, the examiner should identify three or four measurable physical functions, which are currently impaired and can be objectively reassessed 30 minutes or more after the injection. A successful block requires documentation of positive functional changes by trained medical personnel experienced in measuring range of motion or assessing activity performance.

Since these procedures are invasive, less invasive or non-invasive procedures should be considered first. All injections should be preceded by an MRI or a CT scan. Selection of patients, choice of procedure, and localization of the level for injection should be determined by clinical information indicating strong suspicion for pathologic condition(s), compatible MRI findings, and the source of pain symptoms. To qualify for an injection the patient must have at least 3 positive physical exam maneuvers (e.g. Patrick's sign, Faber's test, Ganslen, distraction or gapping, or compression test). Blocks are only appropriate if the patient is eligible for increased therapy, such as a rhizotomy, based on the results of the block.

The evaluator should be acquainted with the patient, in order to determine pre and post values, and preferably unaffiliated with the injectionist's office. Qualified evaluators include nurses, physician assistants, medical assistants, therapists, or non-injectionist physicians. To be successful the results should occur within the expected timeframe and there should be pain relief of approximately 80% demonstrated by pre and post Visual Analog Scale (VAS) scores. Examples of functional changes may include sitting, walking, and lifting. Additionally, a prospective patient completed pain diary must be recorded as part of the medical record that documents response hourly for a minimum requirement of the first 8 hours post injection or until the block has clearly worn off and preferably for the week following an injection. The diary results should be compared to the expected duration of the local anesthetic phase of the procedure. Responses must be identified as to specific body part (e.g., low back, leg pain). The

practitioner must identify the local anesthetic used and the expected duration of response for assessment purposes.

If the first injection does not provide an improvement in function documented by a therapist or a non-injectionist authorized treating physician, and a diagnostic response with temporary and sustained pain relief substantiated by accepted pain scales, (i.e. approximately 80% pain reduction on visual analog scale), similar injections should not be repeated.

Studies have not shown repeat injections to be beneficial in most cases. As pain reports vary among patients, the most important criteria is documentation of functional change. Common examples of functional change include increased range of motion, increased ability to perform job tasks, increased ability to progress in physical therapy, and decreased use of pain medication with increased function. As the purpose of injections is to aid the patient in participating with active therapy to hasten achievement of treatment goals, injections should not be repeated if they are not achieving the more important goals of active therapy and return to work.

Informed decision making should also be documented for injections and 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. The purpose of spinal injections, as well as surgery, is to facilitate active therapy by providing short-term relief through reduction of pain. Patients should be encouraged to express their personal goals, outcome expectations and desires from treatment as well as any personal habits or traits that may be impacted by procedures or their possible side effects. All patients must commit to continuing appropriate exercise with functionally directed rehabilitation usually beginning within 7 days, at the injectionist's discretion. Since most patients with these conditions will improve significantly over time, without invasive interventions, patients must be able to make well-informed decisions regarding their treatment. All injections must be accompanied by active therapy.

Special Requirements for Spinal Therapeutic Injections

Since multi-planar fluoroscopy during procedures is required to document technique and needle placement, an experienced physician should perform the procedure. Injection of contrast dye to assure correct needle placement is required to verify the flow of medication. Permanent images are required to verify needle placement. Unnecessary fluoroscopy procedures should be avoided due to the radiation exposure contributing to cancer risk.

The subspecialty disciplines of the physicians performing the injections may be varied, including, but not limited to: anesthesiology, radiology, surgery, or physiatry. The practitioner should document hands-on training through workshops of the type offered by organizations such as the International Spine Intervention Society (ISIS) with post course proctoring and/or fellowship training with interventional training. They must also be knowledgeable in radiation safety and credentialed by a hospital or surgery center.

Complications

General complications of therapeutic injections may include transient neurapraxia, nerve injury,

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infection, headache, urinary retention, vasovagal effects, epidural hematoma, permanent neurologic damage, dural perforation, cerebrospinal fluid (CSF) leakage, and spinal meningeal abscess. There are reports of direct spinal cord injury due to needle trauma. Permanent paresis, anaphylaxis, arachnoiditis, and death have been rarely reported with the use of epidural steroids.

With steroid injections, there may be a dose-dependent suppression of the hypothalamic-pituitary-adrenal axis lasting between one and three months. Case reports of Cushing Syndrome, hypopituitarism and growth hormone deficiency have been tied to systemic absorption of intra-articular and epidural steroid injections.

Cushing's Syndrome has been reported from serial occipital nerve injections and paraspinal injections. Several cases of spinal epidural lipomatosis have also been reported that may have been caused or exacerbated by spinal steroid injections.

Morning cortisol measurements may be ordered prior to repeat steroid injections or initial spinal steroid injection when the patient has received multiple previous steroid joint injections.

A well-controlled, large retrospective cohort study found that individuals with the same risk factors for osteoporotic fractures were 20% more likely to suffer a lumbar fracture if they had an epidural steroid injection. The risk increased with multiple injections. Thus the risk of epidural injections must be carefully discussed with the patient, particularly for patients over 60, and repeat injections should be generally be avoided unless the functional goals to be reached outweigh the risk for future fracture. Patients with existing osteoporosis or other risk factors for osteoporosis should rarely receive epidural steroid injections.

<u>Contraindications</u>
Absolute contraindications to therapeutic injections include: (a) bacterial infection – systemic or localized to region of injection, (b) bleeding diatheses, (c) hematological conditions, (d) pain of three points or less on a 10-point VAS measurement at the time of injection, e) possible pregnancy, and f) poorly controlled diabetes mellitus for steroid injections.

Relative contraindications to therapeutic injections may include: allergy to contrast, somatization disorders, poorly controlled congestive heart failure (CHF) for steroid injections, risk factors for osteoporosis and uncontrolled hypertension.

Drugs affecting coagulation frequently require restriction from use.

The following are listed in alphabetical order.

F.3.a Epidural Steroid Injection (ESI)

Epidural Steroid Injection (ESI) may include caudal, transforaminal, or interlaminar injections.

Description

Epidural steroid injections are injections of corticosteroid into the epidural space. Purported to reduce pain and inflammation in the acute or sub-acute phases of injury, restoring range of motion and, thereby, facilitating progress in more active treatment programs.

Regarding short-term benefits from injections, there is strong evidence that epidural steroid injections have a small average short term benefit for leg pain and disability for those with sciatica. Additionally, specific to transforaminal injections, there is good evidence that the addition of steroids to a transforaminal bupivacaine injection has a small effect on patient reported pain and disability.

Regarding long-term benefit from injections, there is strong evidence that epidural steroid injections (ESI) do not, on average , provide clinically meaningful long-term improvements in leg pain, back pain, or disability in patients with sciatica (lumbar radicular pain or radiculopathy).

Conversely, there is some evidence that the addition of steroids to a transforaminal bupivacaine injection may reduce the frequency of surgery in the first year after treatment in patients with neurologic compression and corresponding imaging findings, who are strong candidates for surgery and have completed 6 weeks of therapy without adequate benefit. There is some evidence that the benefits for the non-surgical group persisted for at least 5 years in most patients, regardless of the type of block given. An additional study provides some evidence that after 6 weeks of conservative therapy for large herniated discs, an epidural injection may be attempted as it does not compromise the results of a discectomy at a later date. One half of the patients in this study who were randomized to ESIs did not have surgery and this benefit persisted. Because this study did not have a control group who received neither treatment, nor a group which received injections without steroids, one cannot make definite conclusions regarding the efficacy of ESI injections in this setting.

There is strong evidence that ESI has no short or long term benefit for low back pain. A high quality meta-analysis provides additional good evidence against the use of lumbar facet or epidural injections for relief of non-radicular low back pain. Facet injections have very limited therapeutic or diagnostic use. Refer to F.3 Injections –Spinal Therapeutic.

There is some evidence that patients who smoke respond less well to non-operative spine care and that quitting smoking results in greater improvement.

In summary, there is no proven benefit from adding steroids to local anesthetic spinal injections for most injections, with the possible exception of patients who are strong candidates for surgery based on a herniated disc and clear nerve impingement. However, steroids are currently used routinely in spinal injections due to a presumed physiologic effect.

Needle Placement

Multi-planar fluoroscopic imaging is required for all epidural steroid injections. Injection of

contrast dye to assure correct needle placement is required to verify the flow of medication. Permanent images are required to verify needle placement.

Indications

There is strong evidence that epidural injections do not improve long-term outcomes for populations of patients who were diagnosed as having lumbar radicular pain. There is some evidence they may decrease the need for surgery among candidates for nerve decompression and discectomy. In addition, patients can suffer long-term morbidity from injections, although these complications are rare. Therefore, injections are allowed for only a small subset of patients with radicular findings. They may be used for patients who are having significant pain that is interfering with daily functions and the active therapy necessary for recovery despite medical pain management and active therapy. All injections should be preceded by an MRI or a CT scan.

The following sets of patients may have epidural injections, when diagnostic epidural injections are positive:

- When a patient with radicular findings due to herniated disc, meets all of the indications for surgery at approximately 6-8 weeks post active therapy, one epidural may be attempted at the patient's discretion. There is some evidence that after 6 weeks of conservative therapy for large herniated discs an epidural injection may be attempted, as it does not compromise the results of a discectomy at a later date. In this study the initial results of a discectomy were superior to injections and only one half of those receiving injections eventually had surgery.
- For rare acute ruptured (herniated) disc with clear objective radiculopathy if, after one to two weeks of initial oral analgesic and conservative treatment, the patient:
    - has continued pain interfering with most ADL function; and
    - is unable to tolerate the required movements to participate in therapy; and
    - has pain greater in the leg than in the back, generally of 7 or greater on a VAS scale of 10; and
    - has pain following a correlated radicular dermatome; and
    - there is a herniated disc on the MRI at the level of subjective and objective findings; and
    - has either:
        - dural tension signs of straight leg raising or slump test resulting in radicular symptoms correlating with imaging pathology; and/or
        - one of the following documented, reproducible findings, which correlates with the suspected nerve root impingement:
            - Decreased reflexes, or
            - Radicular sensation deficits, or
            - Motor weakness on testing.
- Spinal Stenosis Patients:
    - Patients with radicular findings: When the patient has documented spinal stenosis, has completed 6-8 weeks of active therapy, has persistent radicular findings and difficulty with some activities, thus meeting criteria for surgical intervention, the patient may have one injection for diagnostic purposes. Because stenosis is not

likely to change anatomically, unlike herniated discs which often recede over time, and due to the success rate of surgery for this condition in most cases, early surgical consultation is encouraged whenever the patient remains symptomatic after conservative therapy. If the patient does not wish to have a surgical intervention two additional injections may be provided if the original diagnostic intervention was successful per guideline standards.

- Patients with claudication: The patient has documented spinal stenosis, has completed 6-8 weeks of active therapy, has persistent claudication symptoms and difficulty with some activities, thus meeting criteria for surgical intervention. The patient may have one injection for diagnostic purposes. Patients who have any objective neurologic findings should proceed as the above patient with radicular findings for whom an early surgical consultation is recommended. Refer to C.1. There is some evidence that translaminar steroid injections do not increase walking tolerance for those with spinal stenosis compared to local anesthetic. Those who have mild claudication, or moderate or severe claudication and who do not desire surgery, may continue to receive up to 2 additional injections if the original diagnostic intervention was successful per guideline standards.

Informed decision making should also be documented for injections and 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. The purpose of spinal injections, as well as surgery, is to facilitate active therapy by providing short-term relief through reduction of pain. Patients should be encouraged to express their personal goals, outcome expectations and desires from treatment as well as any personal habits or traits that may be impacted by procedures or their possible side effects. All patients must commit to continuing appropriate exercise with functionally directed rehabilitation usually beginning within 7 days, at the injectionist's discretion. Since most patients with these conditions will improve significantly over time, without invasive interventions, patients must be able to make well-informed decisions regarding their treatment. All injections must be accompanied by active therapy.

It is obligatory that sufficient data be accumulated by the examiner performing this procedure such that the value of the procedure is evident to other reviewers. This entails documentation of patient response regarding the degree and type of response to specific symptoms. As recommended by the ISIS guidelines, the examiner should identify three or four measurable physical functions, which are currently impaired and can be objectively reassessed 30 minutes or more after the injection. A successful block requires documentation of positive functional changes by trained medical personnel experienced in measuring range of motion or assessing activity performance. The evaluator should be acquainted with the patient, in order to determine pre and post values, and preferably unaffiliated with the injectionist's office. Qualified evaluators include nurses, physician assistants, medical assistants, therapists, or non-injectionist physicians. To be successful the results should occur within the expected timeframe and there should be pain relief of approximately 80% demonstrated by pre and post Visual Analog Scale (VAS) scores. Examples of functional changes may include sitting, walking, and lifting. Additionally, a prospective patient completed pain diary must be recorded as part of the medical record that

documents response hourly for a minimum requirement of the first 8 hours post injection or until the block has clearly worn off and preferably for the week following an injection. The diary results should be compared to the expected duration of the local anesthetic phase of the procedure. Responses must be identified as to specific body part (e.g., low back, leg pain). The practitioner must identify the local anesthetic used and the expected duration of response for assessment purposes.

Light sedation and pain relief may be needed for some patients requiring therapeutic injection.

- Time to produce effect: Local anesthetic, less than 30 minutes.
- Frequency: One or more divided levels can be injected in one session. Whether injections are repeated depends upon the patient's response to the previous injection. There is no role for a "series" of 3 injections. Each injection should be judged on the actual functional outcome. Patients with existing osteoporosis or other risk factors for osteoporosis should rarely receive epidural steroid injections (refer to complications section). Subsequent injections may occur after 1 to 2 weeks if patient response has been favorable. Injections can be repeated after a hiatus of six months if the patient has demonstrated functional gain and pain returns or worsens. If the first injection does not provide a diagnostic response of temporary and sustained pain relief (approximately 80% lasting between 2 and 6 weeks) substantiated by accepted pain scales and improvement in function documented preferably by a therapist or non-injectionist authorized physician, similar injections should not be repeated. Patients should complete a pain diary over several days post injection.
- Optimum duration: Usually 1 to 3 injection(s) over a period of six months depending upon each patient's response and functional gain. Most patients will not require 3 injections within 6 months and injections should not be repeated without documented functional change.
- Maximum duration: Up to 4 per year. It is recommended that morning cortisol levels are checked prior to the 3rd or 4th steroid injection. Patients should be reassessed after each injection for evidence of functional improvement and an 80% improvement in pain (as measured by accepted pain scales).

F.3.b Intradiscal Steroid Injections

There is some evidence that intradiscal steroid injection is unlikely to relieve pain or provide functional benefit in patients with non-radicular back pain therefore, they are not recommended. Intradiscal injections of other substances such as bone marrow, stem cells, are not recommended at this time due to lack of evidence and possible complications.

F.3.c Sacroiliac Joint Injection

Description
A generally accepted injection of local anesthetic in an intra-articular fashion into the sacroiliac

joint under fluoroscopic guidance. May include the use of corticosteroids. Long-term therapeutic effect has not yet been established.

Needle Placement

Multi-planar fluoroscopic imaging is required for all steroid injections. Injection of contrast dye to assure correct needle placement is required to verify the flow of medication. Permanent images are required to verify needle placement.

Indications

Insufficient functional progress after 6 months of an appropriate program that includes a combination of active therapy, manual therapy and psychological evaluation and treatment. There should be documented relief from previously painful maneuvers (e.g., Patrick's or Faber's test, Gaenslen, distraction or gapping, and compression test). A positive result from SI joint diagnostic block including improvement in at least three previously identified physical functions. Standards of evaluation should follow those noted in the diagnostic section. Refer to E.2.b. Injections-Diagnostic.

At the minimum, manual therapy, performed on a weekly basis per guideline limits by a professional specializing in manual therapy (such as a doctor of osteopathy or chiropractor) would address any musculoskeletal imbalance causing sacroiliac joint pain such as lumbosacral or sacroiliac dysfunction, pelvic imbalance or sacral base unleveling. This thorough evaluation would include identification and treatment to resolution of all causal conditions such as iliopsoas, piriformis, gluteal or hamstring tonal imbalance, leg length inequality, loss of motion of the sacrum, lumbar spine or pelvic bones, and ligamentous, visceral or fascial restrictions.

An active therapy program would consist of a functionally appropriate rehabilitation program which is advanced in a customized fashion as appropriate commensurate with the patient's level of strength and stability. Such a program would include stretching and strengthening to address areas of muscular imbalance as noted above and neuromuscular re-education to address maintenance of neutral spine via core stabilization with concomitant inhibition of lumbar paravertebral muscles. Patients who demonstrate a directional preference are usually not candidates for this procedure and should receive a trial of directional preference therapy as discussed in section F.13.f Directional Preference.

Informed decision making must be documented including a discussion of possible complications and the likelihood of success. It is suggested that the individual be evaluated by a non-injection specialist to determine whether all reasonable treatment has been attempted and to verify the physical findings. Procedures should not be performed in patients who are unwilling to engage in the active therapy and manual therapy necessary to recover.

Light sedation and pain relief may be needed for some patients requiring therapeutic injection.

- Time to produce effect: Approximately 30 minutes for local anesthetic; 48 to 72 hours for corticosteroid.
- Frequency and optimum duration: 2 to 3 injections per year. Injections may be repeated if they result in increased documented functional benefit for at least 3 months and at least an 80% initial improvement in pain scales as measured by accepted pain scales (such as VAS). At least 6 weeks or 3 months of functional benefit should be obtained with each therapeutic injection. Patients should complete a pain diary over several days post injections.
- Maximum duration: 2 injections per year. It is recommended that morning cortisol levels are checked prior to the 3rd or 4th steroid injection.

F.3.d Transforaminal Injection with Etanercept

Description - Transforaminal injection with a tumor necrosis factor alpha inhibitor is thought to decrease the inflammatory agents which may be associated with the pathophysiology of lumbar radicular pain from a herniated disc.

It is not recommended due to the results of a study which showed no advantage over steroids or saline injections.

F.3.e. Zygapophyseal (Facet) Injection

Description
This is an accepted intra-articular or pericapsular injection of local anesthetic and corticosteroid with very limited uses. There is no justification for a combined facet and medial branch block.

A high quality meta-analysis provides good evidence against the use of lumbar facet or epidural injections for relief of non-radicular low back pain. Facet injections have very limited use. Refer to F.3.a. Injections - Spinal Therapeutic.

Needle Placement
Multi-planar fluoroscopic imaging is required for all steroid injections. Injection of contrast dye to assure correct needle placement is required to verify the flow of medication. Permanent images are required to verify needle placement.

Indications
Patients with pain 1) suspected to be facet in origin based on exam findings and 2) affecting activity; OR patients who have refused a rhizotomy and appear clinically to have facet pain; OR patients who have facet findings with a thoracic component. The physician should document the findings which, for lumbar and cervical spine, consist of pain with extension and lateral bending with referral patterns consistent with the expected pathologic level. In these patients, facet injections may be occasionally useful in facilitating a functionally-directed rehabilitation program and to aid in identifying pain generators. Patients with recurrent pain should be evaluated with more definitive diagnostic injections, such as medial nerve branch injections, to

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determine the need for a rhizotomy. Because facet injections are not likely to produce long-term benefit by themselves and are not the most accurate diagnostic tool, they should not be performed at more than two levels, unilaterally or bilaterally. Due to the lack of proof that these injections improve outcome, prior authorization is required. A high quality meta-analysis provides good evidence against the use of lumbar facet or epidural injections for relief of non-radicular low back pain. All injections should be preceded by an MRI or a CT scan.

Informed decision making should also be documented for injections and 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. The purpose of spinal injections, as well as surgery, is to facilitate active therapy by providing short-term relief through reduction of pain. Patients should be encouraged to express their personal goals, outcome expectations and desires from treatment as well as any personal habits or traits that may be impacted by procedures or their possible side effects. All patients must commit to continuing appropriate exercise with functionally directed rehabilitation usually beginning within 7 days, at the injectionist's discretion. Since most patients with these conditions will improve significantly over time, without invasive interventions, patients must be able to make well-informed decisions regarding their treatment. All injections must be accompanied by active therapy.

It is obligatory that sufficient data be accumulated by the examiner performing this procedure such that the value of the procedure is evident to other reviewers. This entails documentation of patient response regarding the degree and type of response to specific symptoms. As recommended by the ISIS guidelines, the examiner should identify three or four measurable physical functions, which are currently impaired and can be objectively reassessed 30 minutes or more after the injection. A successful block requires documentation of positive functional changes by trained medical personnel experienced in measuring range of motion or assessing activity performance. The evaluator should be acquainted with the patient, in order to determine pre and post values, and preferably unaffiliated with the injectionist's office. Qualified evaluators include nurses, physician assistants, medical assistants, therapists, or non-injectionist physicians. To be successful the results should occur within the expected timeframe and there should be pain relief of approximately 80% demonstrated by pre and post Visual Analog Scale (VAS) scores. Examples of functional changes may include sitting, walking, and lifting. Additionally, a prospective patient completed pain diary must be recorded as part of the medical record that documents response hourly for a minimum requirement of the first 8 hours post injection or until the block has clearly worn off and preferably for the week following an injection. The diary results should be compared to the expected duration of the local anesthetic phase of the procedure. Responses must be identified as to specific body part (e.g., low back, leg pain). The practitioner must identify the local anesthetic used and the expected duration of response for assessment purposes.

Light sedation and pain relief may be needed for some patients requiring therapeutic injection.

- Time to produce effect: Up to 30 minutes for local anesthetic; corticosteroid up to 72 hours.

- Frequency: 1 injection per level with a diagnostic response. A well-controlled, large retrospective cohort study found that individuals with the same risk factors for osteoporotic fractures were 20% more likely to suffer such a lumbar fracture if they had an epidural steroid injection. The risk increased with multiple injections. Thus the risk of epidural injections must be carefully discussed with the patient, particularly for patients over 60, and repeat injections should be generally avoided unless the functional goals to be reached outweigh the risk for future fracture. Patients with existing osteoporosis or other risk factors for osteoporosis should rarely receive steroid injections. It is unknown whether facet steroid injections contribute to increased vertebral fractures, however appropriate caution should be taken for at risk patients as described above. Facet injections may be repeated if they result in increased documented functional benefit for at least 3 months and at least an 80% initial improvement in pain scales as measured by accepted pain scales (such as VAS).
- Optimum duration: 2 injections for each applicable joint per year. Not to exceed 2 joint levels.
- Maximum Duration: 2 per level per year only when at least 3 months of functional benefit is documented. Prior authorization must be obtained for injections beyond two levels. It is recommended that morning cortisol levels are checked prior to the 3rd or 4th steroid injection.

F.4 Injections – Other (Including Radio Frequency)

The following are in alphabetical order.

F.4.a Botulinum Toxin Injections

Description

Used to temporarily weaken or paralyze muscles. These injections may reduce muscle pain in conditions associated with spasticity or dystonia. Neutralizing antibodies develop in at least 4% of patients treated with botulinum toxin type A, rendering it ineffective. Several antigenic types of botulinum toxin have been described. Botulinum toxin type B, first approved by the Food and Drug Administration (FDA) in 2001, is similar pharmacologically to botulinum toxin type A. It appears to be effective in patients who have become resistant to the type A toxin. The immune responses to botulinum toxins type A and B are not cross-reactive, allowing type B toxin to be used when type A action is blocked by antibody. Experimental work with healthy human volunteers suggests that muscle paralysis from type B toxin is not as complete or as long lasting as that resulting from type A. The duration of treatment effect of botulinum toxin type B for cervical dystonia has been estimated to be 12 to 16 weeks. Electromyography (EMG) needle guidance may permit more precise delivery of botulinum toxin to the target area.

There is a lack of adequate evidence supporting the use of these injections to lumbar musculature for the relief of isolated low back pain. There is insufficient evidence to support its use for longer-term pain relief of other myofascial trigger points and it is likely to cause muscle

weakness or atrophy if used repeatedly. Examples of such consequences include subacromial impingement, as the stabilizers of the shoulder are weakened by repeated injections of trigger points in the upper trapezii. Therefore, it is not recommended for use for low back pain or other myofascial trigger points.

They may be used for chronic piriformis syndrome. There is some evidence to support injections for electromyographically proven piriformis syndrome. Prior to consideration of botulimum toxin injection for piriformis syndrome, patients should have had marked (80% or better) but temporary improvement, verified with demonstrated improvement in functional activities, from three separate trigger point injections. To be a candidate for botulinum toxin injection for piriformis syndrome, patients should have had symptoms return to baseline or near baseline despite an appropriate stretching program after trigger point injections. Botulinum toxin injections of the piriformis muscle should be performed by a physician experienced in this procedure and utilize either ultrasound, fluoroscopy, or EMG needle guidance. Botulinum toxin should be followed by limb strengthening and reactivation.

Indications
Piriformis syndrome established by 3 trigger point injections and unrelieved by other therapy.

F.4.b Epiduroscopy and Epidural Lysis of Adhesions

Epiduroscopy and Epidural Lysis of Adhesions is a controversial and investigational treatment of low back pain. It involves the introduction of a fiberoptic endoscope into the epidural space via the sacral hiatus. With cephalad advancement of the endoscope under direct visualization, the epidural space is irrigated with saline. Adhesiolysis may be done mechanically with a fiberoptic endoscope. The saline irrigation is performed with or without epiduroscopy and is intended to distend the epidural space in order to obtain an adequate visual field. It is designed to produce lysis of adhesions, which are conjectured to produce symptoms due to traction on painful nerve roots. Saline irrigation is associated with risks of elevated pressures which may impede blood flow and venous return, possibly causing ischemia of the cauda equina and retinal hemorrhage.

Other complications associated with instrumented lysis include catheter shearing, need for catheter surgical removal, infection (including meningitis), hematoma, and possible severe hemodynamic instability during application. Although epidural adhesions have been postulated to cause chronic low back pain, studies have failed to find a significant correlation between the level of fibrosis and pain or difficulty functioning. Studies of epidural lysis demonstrate no transient pain relief from the procedure. Given the low likelihood of a positive response, the additional costs and time requirement, and the possible complications from the procedure, epiduroscopy, or mechanical lysis, is not recommended.

Epiduroscopy-directed steroid injections are also not recommended because there is no evidence to support an advantage in using an epiduroscope with steroid injections.

F.4.c Prolotherapy

Description
Prolotherapy, also known as sclerotherapy, consists of a series of injections of hypertonic dextrose, with or without glycerine and phenol, into the ligamentous structures of the low back. Its proponents claim that the inflammatory response to the injections will recruit cytokine growth factors involved in the proliferation of connective tissue, stabilizing the ligaments of the low back when these structures have been damaged by mechanical insults.

There is good evidence that prolotherapy alone is not an effective treatment for chronic low back pain. There is some evidence that prolotherapy of the sacroiliac (SI) joint is longer lasting, up to 15 months, than intra-articular steroid injections. The study was relatively small and long-term blinding was unclear, however all injections were done under fluoroscopic guidance. Indications included a 80% reduction in pain from an SI joint injection with local anesthetic, as well as physical findings of SI joint dysfunction. Lasting functional improvement has not been shown and approximately 3 injections were required. The injections are invasive, and may be painful to the patient. The use of prolotherapy for low back pain is generally not recommended, as the majority of patients with SI joint dysfunction will do well with a combination of active therapy and manipulation and not require prolotherapy. However, it may be used in select patients. Prolotherapy is not recommended for other non-specific back pain.

F.4.d Radio Frequency Ablation - Dorsal Nerve Root Ganglion

Due to the combination of possible adverse side effects, time limited effectiveness, and mixed study results, this treatment is not recommended. Refer to the Department's Chronic Pain Disorder Guidelines.

F.4.e Radio Frequency (RF) Denervation - Medial Branch Neurotomy/Facet Rhizotomy

Description
A procedure designed to denervate the facet joint by ablating the corresponding sensory medial branches. Continuous percutaneous radiofrequency is the method generally used. Pulsed radiofrequency should not be used as it may result in incomplete denervation. Cooled radiofrequency is generally not recommended due to current lack of evidence.

There is good evidence in the lumbar spine that carefully selected patients who had 80% relief with medial branch controlled blinded blocks and then had RF neurotomy will have improved pain relief over 6 months and decreased impairment compared to those than those who had sham procedures. Generally pain relief lasts 7-9 months and repeat radiofrequency neurotomy can be successful and last longer. RF neurotomy is the procedure of choice over alcohol, phenol, or cryoablation. Precise positioning of the probe using fluoroscopic guidance is required because the maximum effective diameter of the device is a 5x8 millimeter oval. Permanent images should

be recorded to verify placement of the device.

Needle Placement
Multi-planar fluoroscopic imaging is required for all injections. Injection of contrast dye to assure correct needle placement is required to verify the flow of medication. Permanent images are required to verify needle placement.

Indications
Those patients with proven, significant, facetogenic pain. A minority of low back patients would be expected to qualify for this procedure. This procedure is not recommended for patients with multiple pain generators or involvement of more than 3 levels of medial branch nerves.

Individuals should have met all of the following indications:

- Physical exam findings consistent with facet origin pain, and
- Positive response to controlled medial branch blocks, and
- At least 3 months of pain, unresponsive to 6-8 weeks of conservative therapies, including manual therapy, and
- A psychosocial screening (e.g., thorough psychosocial history, screening questionnaire) with treatment as appropriate has been undergone.

All patients should continue appropriate exercise with functionally directed rehabilitation. Active treatment, which patients will have had prior to the procedure, will frequently require a repeat of the sessions previously ordered (Refer to F.12. Therapy-Active).

It is obligatory that sufficient data be accumulated by the examiner performing this procedure such that the value of the medial branch block is evident to other reviewers. This entails documentation of patient response regarding the degree and type of response to specific symptoms. As recommended by the ISIS guidelines, the examiner should identify three or four measurable physical functions, which are currently impaired and can be objectively reassessed 30 minutes or more after the injection. A successful block requires documentation of positive functional changes by trained medical personnel experienced in measuring range of motion or assessing activity performance. The evaluator should be acquainted with the patient, in order to determine pre and post values, and preferably unaffiliated with the injectionist's office. Qualified evaluators include nurses, physician assistants, medical assistants, therapists, or non-injectionist physicians. To be successful the results should occur within the expected timeframe and there should be pain relief of approximately 80% demonstrated by pre and post Visual Analog Scale (VAS) scores. Examples of functional changes may include sitting, walking, and lifting. Additionally, a prospective patient completed pain diary must be recorded as part of the medical record that documents response hourly for a minimum requirement of the first 8 hours post injection or until the block has clearly worn off and preferably for the week following an injection. The diary results should be compared to the expected duration of the local anesthetic phase of the procedure. Responses must be identified as to specific body part (e.g., low back, leg pain). The practitioner must identify the local anesthetic used and the expected duration of response for assessment purposes.

In almost all cases, this will mean a reduction of pain to 1 or 2 on the 10-point Visual Analog Scale (VAS) correlated with functional improvement. The patient should also identify activities of daily living (ADLs) (which may include measurements of ROM) that are impeded by their pain and can be observed to document objective functional improvement in the clinical setting. Ideally, these activities should be assessed throughout the observation period for function. The observer should not be the physician who performed the procedure. It is suggested that this be recorded on a form similar to ISIS recommendations.

A separate comparative block on a different date should be performed to confirm the level of involvement prior to the rhizotomy. A comparative block uses anesthetics with varying lengths of activity. Medial Branch blocks are probably not helpful to determine the likelihood of success for spinal fusion.

The success rate of radiofrequency neurotomy is likely to decrease with lower percentages of pain relief from a medial branch block.

Informed decision making should also be documented for injections and 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. The purpose of spinal injections, as well as surgery, is to facilitate active therapy by providing short-term relief through reduction of pain. Patients should be encouraged to express their personal goals, outcome expectations and desires from treatment as well as any personal habits or traits that may be impacted by procedures or their possible side effects. All patients must commit to continuing appropriate exercise with functionally directed rehabilitation usually beginning within 7 days, at the injectionist's discretion. Since most patients with these conditions will improve significantly over time, without invasive interventions, patients must be able to make well-informed decisions regarding their treatment. All injections must be accompanied by active therapy.

Complications

Bleeding, infection, or neural injury. The clinician must be aware of the risk of developing a localized neuritis, or rarely, a deafferentation centralized pain syndrome as a complication of this and other neuroablative procedures. Spinal musculature atrophy is likely to occur especially with repeat procedures as a rhizotomy denervates the multifidus-muscle in patients. For this reason repeated rhizotomies and multiple level rhizotomies can be harmful by decreasing supportive spinal musculature. This is especially problematic for younger patients who may engage in athletic activities or workers with strenuous job requirements as the atrophy could result in increased injuries or pain, although this has not been documented.

Post-Procedure Therapy — Active Therapy

Implementation of a gentle aerobic reconditioning program (e.g., walking) and back education within the first post-procedure week, barring complications. Instruction and participation in a long-term home-based program of ROM, core strengthening, postural or neuromuscular re-education, endurance, and stability exercises should be accomplished over a period of four to ten

visits post-procedure. Patients who are unwilling to engage in this therapy should not receive this procedure.

Requirements for Repeat Radiofrequency Medial Branch Neurotomy
In some cases pain may recur. Successful RF Neurotomy usually provides from six to eighteen months of relief.

Due to denervation of spinal musculature repeated rhizotomies should be limited. Refer to the Department's Chronic Pain Disorder Guidelines.

Before a repeat RF Neurotomy is done, a confirmatory medial branch injection should be performed if the patient's pain pattern presents differently than the initial evaluation. In occasional patients, additional levels of RF neurotomy may be necessary. The same indications and limitations apply

F.4.f Radio Frequency Denervation - Sacro-iliac (SI) Joint Cooled

This procedure requires neurotomy of multiple nerves, L5 dorsal ramus, and lateral branches of S1-S3 under C-arm fluoroscopy. There is good evidence that cooled RF neurotomy performed in a highly selected population results in better pain relief and functional gains than a sham procedure. The benefits persisted for 9 months. Approximate half of the patients had benefits initially and approximately half of those reported the pain was completely relieved.

Needle Placement
Multi-planar fluoroscopic imaging is required for all steroid injections. Injection of contrast dye to assure correct needle placement is required to verify the flow of medication. Permanent images are required to verify needle placement.

Indications
The following three requirements must be fulfilled:

1. The patient has physical exam findings of at least 3 positive physical exam maneuvers (e.g. Patrick's sign, Faber's test, Ganslen distraction or gapping, or compression test). Insufficient functional progress after 6 months of an appropriate program that includes a combination of active therapy, manual therapy and psychological evaluation and treatment.

   At the minimum, manual therapy performed on a weekly basis per guideline limits by a professional specializing in manual therapy (such as a doctor of osteopathy or chiropractor) would address any musculoskeletal imbalance causing sacroiliac joint pain such as lumbosacral or sacroiliac dysfunction, pelvic imbalance or sacral base unleveling. This thorough evaluation would include identification and treatment to resolution of all causal conditions such as iliopsoas, piriformis, gluteal or hamstring tonal imbalance, leg length inequality, loss of motion of the sacrum, lumbar spine or pelvic bones, and ligamentous, visceral or fascial restrictions.

An active therapy program would consist of a functionally appropriate rehabilitation program which is advanced in a customized fashion as appropriate commensurate with the patient's level of strength and stability. Such a program would include stretching and strengthening to address areas of muscular imbalance as noted above and neuromuscular re-education to address maintenance of neutral spine via core stabilization with concomitant inhibition of lumbar paravertebral muscles. Patients who demonstrate a directional preference are usually not candidates for this procedure and should receive a trial of directional preference therapy as discussed in section F.12.f. Directional Preference. Patients with confounding findings suggesting zygapophyseal joint or intervertebral disc pain generators should be excluded.

2. Two fluoroscopically guided comparative blocks of the appropriate branches with differing anesthetics, 80% relief of pain for the appropriate time periods, and functional improvement must be documented to meet standards for control blocks. Refer to F 3 C Sacroiliac Joint Injection.

   It is obligatory that sufficient data be accumulated by the examiner performing this procedure such that the value of the procedure is evident to other reviewers. This entails documentation of patient response regarding the degree and type of response to specific symptoms. The examiner should identify three or four measurable provocative physical exam maneuvers (e.g. Patrick's sign, Faber's test, Gaenslen, distraction or gapping, or compression test), and physical functions, which are currently impaired and can be objectively reassessed 30 minutes or more after the injection. A successful block requires documentation of positive functional changes by trained medical personnel experienced in measuring range of motion or assessing activity performance. The evaluator should be acquainted with the patient, in order to determine pre and post values, and preferably unaffiliated with the injectionist's office. Qualified evaluators include nurses, physician assistants, medical assistants, therapists, or non-injectionist physicians. To be successful the results should occur within the expected timeframe and there should be pain relief of approximately 80% demonstrated by pre and post Visual Analog Scale (VAS) scores. Examples of functional changes may include sitting, walking, and lifting. Additionally, a prospective patient completed pain diary must be recorded as part of the medical record that documents response hourly for a minimum requirement of the first 8 hours post injection or until the block has clearly worn off and preferably for the week following an injection. The diary results should be compared to the expected duration of the local anesthetic phase of the procedure. Responses must be identified as to specific body part (e.g., low back, leg pain). The practitioner must identify the local anesthetic used and the expected duration of response for assessment purposes.

3. Informed decision making must be documented including a discussion of possible complications and the likelihood of success. It is suggested that the individual be evaluated by a non-injection specialist to determine whether all reasonable treatment has been attempted and to verify the physical findings. Procedures should not be performed

in patients who are unwilling to engage in the active therapy necessary to recover.

Complications
Damage to sacral nerve roots – issues with bladder dysfunction etc. Bleeding, infection, or neural injury. The clinician must be aware of the risk of developing a localized neuritis, or rarely, a deafferentation centralized pain syndrome as a complication of this and other neuroablative procedures.

Post-Procedure Therapy — Active Therapy:
Implementation of a gentle aerobic reconditioning program (e.g., walking) and back education within the first post-procedure week, barring complications. Instruction and participation in a long-term home-based program of ROM, core strengthening, postural or neuromuscular re-education, endurance, and stability exercises should be accomplished over a period of four to ten visits post-procedure. Patients who are unwilling to engage in this therapy should not receive this procedure.

Requirements for Repeat Radiofrequency SI Joint Neurotomy
In some cases pain may recur. Successful RF Neurotomy usually provides from six to eighteen months of relief. Repeat neurotomy should only be performed if the initial procedure resulted in improved function for 6 months.

Due to denervation of spinal musculature repeated rhizotomies should be limited.

F.4.g Transdiscal Biacuplasty

Transdiscal biacuplasty is a cooled radiofrequency procedure intended to coagulate fissures in the disc and surrounding nerves which could be pain generators.

It is not recommended due to lack of published data demonstrating effectiveness.

F.4.h Trigger Point Injections and Dry Needling Treatment

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 efficacy can be enhanced if injections 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 conflicting evidence regarding the benefit of trigger point injections. A truly blinded study comparing dry needle treatment of trigger points is not feasible. There is no evidence that injection of medications improves the results of trigger-point injections. Needling alone may account for some of the therapeutic response. Needling must be performed by practitioners with the appropriate training, credentialing and licensing in accordance with state and other applicable regulations.

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

Indications

Trigger point injections are a generally accepted treatment. Trigger point injections 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 throughout the time period they are undergoing intensive myofascial interventions. Myofascial pain is often associated with other underlying structural problems and any abnormalities need to be ruled out prior to injection.

Trigger point injections are indicated in those patients where well circumscribed trigger points have been consistently observed, demonstrating a local twitch response, characteristic radiation of pain pattern and local autonomic reaction, such as persistent hyperemia following palpation. Generally, these injections are not necessary unless consistently observed trigger points are not responding to specific, noninvasive, myofascial interventions within approximately a 6-week timeframe. However, trigger point injections may be occasionally effective when utilized in the patient with immediate, acute onset of low back pain.

Complications

Potential but rare complications of trigger point injections include infection, pneumothorax, anaphylaxis, penetration of viscera, neurapraxia, and neuropathy. If corticosteroids are injected in addition to local anesthetic, there is a risk of local myopathy. Severe pain on injection suggests the possibility of an intraneural injection, and the needle should be immediately repositioned. Time to produce effect: Local anesthetic 30 minutes; 24 to 48 hours for no anesthesia.

- Frequency: Weekly. Suggest no more than 4 injection sites per session per week to avoid significant post-injection soreness.
- Optimum duration: 4 Weeks.
- Maximum duration: 8 weeks. Occasional patients may require 2 to 4 repetitions of trigger point injection series over a 1 to 2 year period.

F.5 Medications

Medications use in the treatment of low-back injuries is appropriate for controlling acute and chronic pain and inflammation. Use of medications will vary widely due to the spectrum of injuries, from simple strains to post-surgical healing. 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 of prescription and over-the-counter medications as well as the contents of over-the-counter herbal products. The medication lists below do not provide complete information on side effects or drug interactions. Providers should seek information from other sources for details.

The following are listed in alphabetical order.

F.5.a 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 contain acetaminophen. The total daily dose of acetaminophen is recommended not to exceed three grams per 24-hour period, from all sources, including narcotic-acetaminophen combination preparations.

- Optimum Duration: 7 to 10 days.
- Maximum Duration: Extended use as indicated on a case-by-case basis. Use of this substance long-term (for 3 days per week or greater) may be associated with rebound pain upon cessation.

F.5.b Antibiotics for Chronic Pain Secondary to Disc Herniation

Description

Several studies have documented the presence of bacteria in herniated disc nucleus tissue removed surgically. It had been postulated that Modic type 1 changes could be secondary to bacterial infection. There is good evidence from one study that chronic pain patients with Modic type 1 changes in discs adjacent to the initial disc herniation after 6 months of treatment can experience decreased pain and disability after a 100 day course of amoxicillin-clavulanate (one or two 500mg/125mg 3x per day). Modic type one changes demonstrate decreased intensity on T1 spin echo weighted images and increase intensity on T2 spin echo weighted images. Modic changes consistent with this definition qualify for treatment. The antibiotic course is similar to that prescribed for post-operative discitis. Both non-surgical and surgical patients were included in the study and radicular symptoms could be present or pain could be limited to axial pain. Patients were instructed not to exercise during the treatment period. Most patients reported decreased pain at night and no longer having constant pain. Improvement in pain and disability started at about 6 weeks, increased over time and persisted at 1 year. Some patients stopped therapy due to side effects.

Complications

Complications include those related to long-term antibiotic therapy.

Indications

- Modic type 1 changes at adjacent vertebra at the time of treatment initiation.
- 6 to 24 months of pain with an average of 6/10 (calculate average by using the worst reported pain within the last 2 weeks, current pain, and usual pain in the last 2 weeks)
- Pain interferes with function, e.g., not able to return to full duty
- Use of chronic opioids to control pain
- No contraindications to antibiotic use.

F.5.c Intravenous Steriods

The benefits of preventing neurological damage from acute spinal cord compression in an emergent situation may outweigh the risks of pharmacologic side effects from steroids.

F.5.d Glucosamine

There is good evidence that glucosamine does not improve pain related disability in those with chronic low back pain and degenerative changes on radiologic studies; therefore, it is not recommended for chronic lumbar spinal or non-joint pain.

F.5.e Muscle Relaxants

Muscle Relaxants are appropriate for muscle spasm with pain. There is strong evidence that non-benezodiazepine muscle relaxants are more effective than placebo for providing short-term pain relief in acute low back 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. A number of muscle relaxants interact with other medications.

- Optimum Duration: 1 week.
- Maximum Duration: 2 weeks (or longer if used only at night).

F.5.f Non-Selective Non-Steroidal Anti-Inflammatory Drugs

Useful for pain and inflammation. In mild cases, they may be the only drugs required for analgesia. There are several classes of NSAIDs, and 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 those 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 acetaminophen use. Chronic use of NSAIDs is generally not recommended due to increased risk of cardiovascular events and GI bleeding.

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 six months in patients on chronic NSAIDs and initially when indicated.

Non-Selective Non-Steroidal Anti-Inflammatory Drugs
Includes NSAIDs and acetylsalicylic acid (aspirin). Serious GI toxicity, such as bleeding, perforation, and ulceration can occur at any time, with or without warning symptoms, in patients treated with traditional NSAIDs. Physicians should inform patients about the signs and/or symptoms of serious GI toxicity and what steps to take if they occur. Anaphylactoid reactions may occur in patients taking NSAIDs. NSAIDs may interfere with platelet function. Fluid retention and edema have been observed in some patients taking NSAIDs.

- Optimum duration: 1 week.
- Maximum duration: 1 year. Use of these substances long-term (3 days per week or greater) is associated with rebound pain upon cessation.

Selective Cyclo-oxygenase-2 (COX-2) Inhibitors
COX-2 inhibitors differ from the traditional NSAIDs in adverse side effect profiles. The major advantages of selective COX-2 inhibitors over traditional NSAIDs are that they have less GI toxicity and no platelet effects. COX-2 inhibitors can worsen renal function in patients with renal insufficiency; thus, renal function may need monitoring.

COX-2 inhibitors should not be first-line for low risk patients who will be using an NSAID short-term but are indicated in select patients for whom traditional NSAIDs are not tolerated. Serious upper GI adverse events can occur even in asymptomatic patients. Patients at high risk for GI bleed include those who use alcohol, smoke, are older than 65, take corticosteroids or anti-coagulants, or have a longer duration of therapy. Celecoxib is contraindicated in sulfonamide allergic patients.

- Optimum duration: 7 to 10 days.

- Maximum Duration: Chronic use is appropriate in individual cases. Use of these substances long-term (3 days per week or greater) is associated with rebound pain upon cessation

F.5.g Opioids

Opioids should be reserved for the treatment of acute severe low back pain. There are circumstances where prolonged use of opioids is justified based on diagnosis and severity of functional deficits, and in these cases, it should be documented and justified. In mild to moderate cases of low back 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 scale 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.

- Optimum Duration: 3 to 7 days.
- Maximum Duration: 2 weeks. Use beyond 2 weeks is acceptable in appropriate cases. Refer to the Department's Chronic Pain Disorder Guideline, which gives a detailed discussion regarding medication use in chronic pain management. Use beyond 30 days after non-traumatic injuries, or 6 weeks post-surgery after the original injury or post operatively is not recommended. If necessary the physician should access the Montana Prescription Drug Registry and follow recommendations in Chronic Pain Guideline. This system allows the prescribing physician to see most of the controlled substances prescribed by other physicians for an individual patient.

F.5.h Oral Steroids

Oral Steroids have limited use but are accepted in cases requiring potent anti-inflammatory drug effect. Two studies were identified for the treatment of herniated discs that did not qualify for evidence however both used comparison placebo groups and neither showed any long-term benefit regarding pain or disability. There is no adequate evidence supporting oral steroids for patients with low back pain with or without radiculopathy, significant side effects are possible, and they are not generally recommended.

F.5.i 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 doses, are useful for chronic neurogenic pain with difficulty sleeping but have more frequent side effects.

Anti-anxiety medications are best used for short-term treatment (i.e., less than 6 months). Accompanying sleep disorders are best treated with sedating anti-depressants prior to bedtime. Frequently, combinations of the above agents are useful. 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 Department's Chronic Pain Disorder Guidelines, which give a detailed discussion regarding medication use in chronic pain management.

- Optimum Duration: 1 to 6 months.
- Maximum Duration: 6 to 12 months, with monitoring.

F.5.j Tramadol

May be useful in the relief of low back 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. It is not considered a controlled substance in the U.S. 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. Because it inhibits the reuptake of norepinephrine and serotonin, use with other agents that increase norepinephrine and/or serotonin (e.g. SNRIs, mirtazapine, TCAs, SSRIs) can result in serotonin syndrome. This medication has physically addictive properties, and withdrawal may follow abrupt discontinuation; thus, it is not generally recommended for those with prior opioid addiction.

- Optimum Duration: 3 to 7 days.
- Maximum Duration: 2 weeks. Use beyond 2 weeks is acceptable in appropriate cases.

F.6 Interdisciplinary Rehabilitation Programs

This is the gold standard of treatment for individuals with low back pain who have not responded to less intensive modes of treatment. There is good evidence that interdisciplinary programs which 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 Department recommends consideration of referral to an interdisciplinary program within six 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 use of other drugs of abuse 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 Department 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: To ensure positive functional outcomes, consistent and coordinated communication among the injured worker, the medical providers, the insurer and the employer is essential. It is also essential to protect the injured worker's privacy. Care decisions should be communicated.

- Documentation: Through documentation by all professionals involved and/or discussions with the patient, it should be clear that functional goals are being actively pursued and measured on a regular basis to determine their achievement or need for modification.

- Treatment Modalities: Use of modalities may be necessary early in the process to facilitate compliance with and tolerance to therapeutic exercise, physical conditioning, and increasing functional activities. Active treatments should be emphasized over passive treatments. Active and self-monitored passive treatments should encourage self-coping skills and management of pain, which can be continued independently at home or at work. Treatments that can foster a sense of dependency by the patient on the caregiver should be avoided. Treatment length should be decided based upon observed functional improvement. For a complete list of active and passive therapies, refer to F.12. Therapy – Active and F.13. Therapy – Passive. All treatment timeframes may be extended based on the patient's positive functional improvement.

- Therapeutic Exercise Programs: A therapeutic exercise program should be initiated at the start of any treatment rehabilitation. Such programs should emphasize education, independence, and the importance of an ongoing exercise regimen. There is good evidence that exercise alone or part of a multi-disciplinary program results in decreased disability for workers with non-acute low back pain. There is not sufficient evidence to support the recommendation of any particular exercise regimen over any other exercise regimen.

- Return to Work: The authorized treating physician should continually evaluate the patient for their potential to return to work. For patients currently employed, efforts should be aimed at keeping them employed. Formal rehabilitation programs should provide assistance in creating work profiles. For more specific information regarding retorn to work, refer to F.11 Return to Work in this guideline.

- For patients currently employed, efforts should be aimed at keeping them employed. Formal rehabilitation programs should provide assistance in creating work profiles. For more specific information regarding return to work, refer to F.11. Return to Work.

- Patient Education: Patients with pain need to re-establish a healthy balance in lifestyle. All providers should educate patients on how to overcome barriers to resuming daily activity, including pain management, decreased energy levels, financial constraints, decreased physical ability, and change in family dynamics.

- Psychosocial Evaluation and Treatment: Psychosocial evaluation should be initiated, if not previously done. Providers of care should have a thorough understanding of the patient's personality profile, especially if dependency issues are involved. Psychosocial treatment may enhance the patient's ability to participate in pain treatment rehabilitation, manage stress, and increase their problem-solving and self-management skills.

- Vocational Assistance: Vocational assistance can define future employment opportunities or assist patients in obtaining future employment. Refer to F.11 Return to Work for detailed information.

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.

F.6.a 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; or 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 or 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), 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.

- Time to Produce Effect: 3 to 4 weeks.

- Frequency: Full time programs – No less than 5 hours per day, 5 days per week; part-time programs – 4 hours per day, 2–3 days per week.

- Optimum Duration: 3 to 12 weeks at least 2–3 times a week. Follow-up visits weekly or every other week during the first 1 to 2 months after the initial program is completed.

- Maximum Duration: 4 months for full-time programs and up to 6 months for part-time programs. Periodic review and monitoring thereafter for 1 year, and additional follow-up based on the documented maintenance of functional gains.

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 that 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.

- Time to Produce Effect: 2 weeks.
- Frequency: 2 to 5 visits per week, up to 8 hours per day.
- Optimum Duration: 2 to 4 weeks.
- Maximum Duration: 6 weeks. Participation in a program beyond 6 weeks must be documented with respect to need and the ability to facilitate positive symptomatic and functional gains

Spinal Cord Programs:
Spinal Cord Systems of Care provide coordinated, case-managed, and integrated services for people with spinal cord dysfunction, whether due to trauma or disease. The system includes an inpatient component in an organization licensed as a hospital, as well as an outpatient component. Each component endorses the active participation and choice of the persons served throughout the entire program. The Spinal Cord System of Care also provides or formally links with key components of care that address the lifelong needs of the persons served.

This can include a highly structured program involving a team approach or can involve any of the components thereof. The interdisciplinary team should, at a minimum, be comprised of a

qualified medical director who is board certified and trained in rehabilitation, a case manager, an occupational therapist, a physical therapist, a psychologist, a rehabilitation RN and MD, and a therapeutic recreation specialist. As appropriate, the team may also include: a rehabilitation counselor, a respiratory therapist, a social worker, or a speech-language pathologist.

Timeframe durations for any spinal cord program should be determined based on the extent of the patient's injury and at the discretion of the rehabilitation physician in charge.

Opioid/Chemical Treatment Programs
Refer to the Department's Chronic Pain Disorder Guideline.

F.6.b Informal Interdisciplinary Rehabilitation Programs

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 Department 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. To ensure positive functional outcomes, consistent and coordinated communication among the injured worker, the medical providers, the insurer and the employer is essential. It is also essential to protect the injured worker's privacy. Care decisions should be communicated.

- Time to Produce Effect: 3 to 4 weeks.
- Frequency: Full-time programs – No less than 5 hours per day, 5 days per week; Part-time programs – 4 hours per day for 2–3 days per week.
- Optimum Duration: 3 to 12 weeks at least 2–3 times a week. Follow-up visits weekly or every other week during the first 1 to 2 months after the initial program is completed.
- Maximum Duration: 4 months for full-time programs and up to 6 months for part-time programs. Periodic review and monitoring thereafter for 1 year, and additional follow-up based upon the documented maintenance of functional gains.

F.7. Orthotics

F.7.a Foot Orthoses and Inserts

Foot Orthoses and Inserts are accepted interventions for spinal disorders that are due to aggravated mechanical abnormalities, such as leg length discrepancy, scoliosis, or lower extremity misalignment. Shoe insoles or inserts may be effective for patients with acute low back problems who stand for prolonged periods of time. A trial of taping may be performed first to evaluate the likely effect of an orthotic.

F.7.b Lumbar Support Devices

Lumbar Support Devices include backrests for chairs and car seats. Lumbar supports may provide symptomatic relief of pain and movement reduction in cases of chronic low back problems. Lumbar support devices can be utilized to maintain physiologically correct posture of the spine. Lumbar supports should usually be approximately 1.5" in thickness to maintain the natural lordosis of the lumbar spine, but may depend on patient size and firmness of support.

F.7.c Lumbar Corsets and Back Belts

There is insufficient evidence to support their use. They are an accepted treatment with limited application. The injured worker should be advised of the potential harm from using a lumbar support for a period of time greater than that for which it is prescribed. Harmful effects include de-conditioning of the trunk musculature, skin irritation, and general discomfort.

F.7.d Lumbosacral Bracing

Rigid bracing devices are well-accepted and commonly used for post-fusion, scoliosis, and vertebral fractures. Use of the rigid bracing should generally not exceed twelve weeks secondary to possible de-conditioning of the trunk musculature. Sacroiliac belts may be indicated for short durations to assist with stability of the SI joint.

F.8 Education/Informed Decision Making

Education/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 low back pain and disability. Unfortunately, practitioners often think of education and informed decision making last, after medications, manual therapy, and surgery.

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

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improvement in pain or other physical function. There is some evidence that a 2 day course focusing on the biopsychosocial model with an emphasis on the goals of returning to usual activities and fitness is as effective in reducing disability as six manual therapy sessions provided by physiotherapists and more limited patient education. 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 patient 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. One study indicated that information provided only by video might not be 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.

- Time to produce effect: Varies with individual patient
- Frequency: Should occur at every visit.

F.9 Personality/Psychological/Psychosocial 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 low back 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.

A psychologist with a PhD, PsyD, EdD credentials, or a psychiatric MD/DO may perform psychosocial treatments. Other licensed mental health providers or licensed health care providers with training in cognitive behavior therapy (CBT) (for example, LCSW, RN, etc.) or certified as CBT therapists working in consultation with or referral from a PhD, PsyD, EdD, or psychiatric MD/DO; and with experience in treating chronic pain disorders in injured workers may also perform treatment.

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. The CBT used in research studies is often "manualized CBT," meaning that the treatment follows a specific protocol in a manual. In clinical settings, CBT may involve the use of standardized materials, but it is also commonly adapted by a psychologist or psychiatrist to the patient's unique circumstances. If the CBT is being performed by a non-mental health professional, a manual approach would be strongly recommended. CBT must be distinguished from neuropsychological therapies used to teach compensatory strategies to brain injured patients, which are also called "cognitive therapy."

It should be noted that most clinical trials on CBT exclude subjects who have significant psychiatric diagnoses. Consequently, the selection of patients for CBT should include the following considerations. CBT is instructive and structured, using an educational model with homework to teach inductive rational thinking. Because of this educational model, a certain level

of literacy is assumed for most CBT protocols. Patients who lack the cognitive and educational abilities required by a CBT protocol are unlikely to be successful. Further, given the highly structured nature of CBT, it is more effective when a patient's circumstances are relatively stable. For example, if a patient is about to be evicted, is actively suicidal, or is coming to sessions intoxicated, these matters will generally preempt CBT treatment for pain, and require other types of psychotherapeutic response. Conversely, literate patients whose circumstances are relatively stable, but who catastrophize or cope poorly with pain or disability are often good candidates for CBT for pain. Similarly, literate patients whose circumstances are relatively stable, but who exhibit unfounded medical phobias, are often good candidates for CBT for anxiety.

There is good evidence that cognitive intervention reduces low back disability in the short term and in the long term. In one of the studies the therapy consisted of 6, 2-hour sessions given weekly to workers who had been sick-listed for 8-12 weeks. Comparison groups included those who received routine care. There is good evidence that psychological interventions, especially CBT, are superior to no psychological intervention for chronic low back pain, and that self-regulatory interventions, such as biofeedback and relaxation training, may be equally effective. There is good evidence that six group therapy sessions lasting one and a half hours each focused on CBT skills improved function and alleviated pain in uncomplicated sub-acute and chronic low back pain patients. There is some evidence that CBT provided in seven two-hour small group sessions can reduce the severity of insomnia in chronic pain patients. A Cochrane meta-analysis grouped very heterogenous behavioral interventions and concluded that there was good evidence that CBT may reduce pain and disability but the effect size was uncertain. In total, the evidence clearly supports CBT, and it should be offered to all chronic pain patents who do not have other serious issues, as discussed above.

CBT is often combined with active therapy in an interdisciplinary program, whether formal or informal. It must be coordinated with a psychologist or psychiatrist. CBT can be done in a small group or individually, and the usual number of treatments varies between 8 and16 sessions.

In conjunction with CBT, the patient must have a full psychological evaluation.

Psychological Diagnostic and Statistical Manual of Mental Disorders (DSM) Axis I disorders are common in chronic pain. One study demonstrated that the majority of patients who had failed other therapy and participated in an active therapy program also suffered from major depression. However, in a program that included CBT and other psychological counseling, the success rate for return to work was similar for those with and without a DSM IV diagnosis. This study further strengthens the argument for having some psychological intervention included in all chronic pain treatment plans.

For all psychological/psychiatric interventions, an assessment and treatment plan with measurable behavioral goals, timeframes, and specific interventions planned, must be provided to the treating physician prior to initiating treatment. A status report must be provided to the authorized treating physician every two weeks during initial more frequent treatment and

monthly thereafter. The report should provide documentation of progress toward functional recovery and a discussion of the psychosocial issues affecting the patient's ability to participate in treatment. The report should also address pertinent issues such as pre-existing, aggravated, and/or causative issues, as well as realistic functional prognosis.

F.9.a Cognitive Behavioral Therapy (CBT) or Similar Treatment:

- Time to Produce Effect: 6 to 8 1–2 hour session, group or individual (1-hour individual or 2-hour group).
- Maximum Duration: 16 sessions.

Note:
In conjunction with CBT the patient must have a full psychological evaluation.

F.9.b Other Psychological/Psychiatric Interventions

- Time to Produce Effect: 6 to 8 weeks.
- Frequency: 1 to 2 times weekly for the first 2 weeks (excluding hospitalization, if required), decreasing to 1 time per week for the second month. Thereafter, 2 to 4 times monthly with the exception of exacerbations, which may require increased frequency of visits. Not to include visits for medication management
- Optimum Duration: 2 to 6 months.
- Maximum Duration: 6 months. Not to include visits for medication management. For select patients, longer supervised psychological/psychiatric treatment may be required, especially if there are ongoing medical procedures or complications. If counseling beyond 6 months is indicated, the management of psychosocial risks or functional progress must be documented. Treatment plan/progress must show severity.

F.10 Restriction of Activities

Continuation of normal daily activities is the recommendation for low back pain patients since immobility will negatively affect rehabilitation. Prolonged immobility results in a wide range of deleterious effects, such as a reduction in aerobic capacity and conditioning, loss of muscle strength and flexibility, increased segmental stiffness, promotion of bone demineralization, impaired disc nutrition, and the facilitation of the illness role.

Immobility may range from bed rest to the continued use of orthotics, such as lumbar support braces. 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. There is strong evidence against the use of bed rest in acute low back pain cases without neurologic symptoms. Activity should be increased based on the improvement of core strengthening.

Patients should be educated regarding the detrimental effects of immobility versus the

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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 with low back pain.

F.11 Return to Work

Return to work and/or work-related activities whenever possible is one of the major components in low back pain management and rehabilitation. There is some evidence that an integrated care program including 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 reduction of pain. 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. At 21 days of absence from work, an injured worker should be considered for return to work/stay at work intervention. 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.

The Montana Department of Labor and Industry and workers' compensation insurers help Montana workers stay at work or return to work quickly after a work-related injury. Assistance can be requested by phone 406-444-1752 or by email at sawrtwrquest@mt.gov.

Two counseling sessions with an occupational physician, and worksite visit if necessary, may be helpful for workers who are concerned about returning to work. Another study found that low back pain claimants who received information on self-care and return to work had fewer episodes of relapse than those who did not receive the advice.

At least one study suggest that health status is worse for those who do not return to work than those who do. Self-employment and injury severity predict return to work. Difficulty with pain control, ADLs, and anxiety and depression were common.

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

F.11.a Job History Interview

The authorized treating physician should perform a job history interview at the time of the initial evaluation and before any plan of treatment is established. Documentation should include the

workers' job demands, stressors, duties of current job, and duties of job at the time of the initial injury. In addition, cognitive and social issues should be identified, and treatment of these issues should be incorporated into the plan of care.

F.11.b Coordination of Care

Management of the case is a significant part of return to work and may be the responsibility of the authorized treating physician, occupational health nurse, risk manager, or others. Case management is a method of communication between the primary provider, referral providers, insurer, employer, and employee. Because case management may be coordinated by a variety of professionals, the case manager should be identified in the medical record.

F.11.c Communication

To ensure positive functional outcomes, consistent and coordinated communication among the injured worker, the medical providers, the insurer and the employer is essential. It is also essential to protect the injured worker's privacy. Care decisions should be communicated.

The Medical Status Form (MSF) is a coordinated and consistent mechanism for communication among the injured worker, the medical provider, the insurer and the employer regarding the work abilities of the injured worker including any limitations and restrictions. The treating physician is required to complete the form for every visit. It is recommended the MSF be discussed with the injured worker. The MSF should be distributed as follows:

- Page 1 (white) is retained by the treating physician
- Page 2 (yellow) is sent to the adjustor/insurer
- Page 3 (pink) is given to the injured to take to the employer (the personal medical information is redacted from the bottom of the form)

F.11.d Establishment of Return to Work Status

Return to work for persons with chronic pain should be considered therapeutic, assuming that work is not likely to aggravate the basic problem or increase the discomfort. In most cases of chronic pain, the worker may not be currently working or even employed. The goal of return to work would be to implement a plan of care to return the worker to any level of employment with the current employer or to return him/her to any type of new employment.

F.11.e Establishment of Activity Level Restrictions

A formal job description for the injured worker is necessary to identify physical demands at work and assist in the creation of modified duty. A jobsite evaluation may be utilized to identify applicable tasks such as pushing, pulling, lifting, reaching, grasping, pinching, sitting, standing, posture, ambulatory distance and terrain, and if applicable, environment for temperature, air flow, noise, and the number of hours that may be worked per day. Due to the lack of predictability regarding exacerbation of symptoms affecting function, an extended,

occupationally focused functional capacity evaluation may be necessary to determine the patient's tolerance for job type tasks over a continued period of time. Job requirements should be reviewed for the entire 8 hours or more of the working day. Between one and three days after the evaluation, there should be a follow-up evaluation by the treating therapist and/or the authorized treating physician to assess the patient's status. When prescribing the FCE, the physician must assess the probability of return to work against the potential for exacerbation of the work related condition. Work restrictions assigned by the authorized treating physician may be temporary or permanent. The case manager should continue to seek out modified work until restrictions become less cumbersome or as the worker's condition improves or deteriorates.

F.11.f Rehabilitation and Return to Work

As part of rehabilitation, every attempt should be made to simulate work activities so that the authorized treating physician may promote adequate job performance. The use of ergonomic or adaptive equipment, therapeutic breaks, and interventional modalities at work may be necessary to maintain employment

F.11.g Vocational Assistance

Formal vocational rehabilitation is a generally accepted intervention and can assist disabled persons to return to viable employment. Assisting patients to identify vocational goals will facilitate medical recovery and aid in the achievement of MMI by (1) increasing motivation towards treatment and (2) alleviating the patient's emotional distress. Chronic low back pain patients will benefit most if vocational assistance is provided during the interdisciplinary rehabilitation phase of treatment. To assess the patient's vocational capacity, a vocational assessment utilizing the information from occupational and physical therapy assessments may be utilized to identify rehabilitation program goals, as well as optimize both patient motivation and utilization of rehabilitation resources. This may be extremely helpful in decreasing the patient's fear regarding an inability to earn a living, which can add to his/her anxiety and depression.

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. It is suggested that case managers be accessed through their payer or third-party administrator. 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 Department 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.

F.12 Therapy - Active

The following active therapies are widely used and accepted methods of care for a variety of work-related injuries. A retrospective cohort study suggests that early referral to rehabilitation/physical therapy, within 14 days decreases the cost and likelihood of the need for later referrals and testing, thus decreasing overall medical costs. Active therapies are based on the philosophy that therapeutic exercise and/or activities are beneficial for restoring flexibility, strength, endurance, function, ROM, and alleviating discomfort. Active therapy requires an internal effort by the individual 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). The supervision may include 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 is predominately executed by the patient.

Education and counseling should include 1) understanding of the strength inherent in the human spine, and stabilization musculature including the transversus abdominis and multifidus, 2) how neuroscience explains pain perception, 3) the favorable prognosis of low back pain, 4) use of active pain coping strategies that decrease fear and catastrophizing, 5) early resumption of normal activities while still experiencing pain, and 6) the importance of increasing activity levels. 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. The patient's baseline and progress should be measured using validated tools such as the Oswestry Disability Index or the Roland –Morris Disability Questionnaire or following objective functional measurements.

Therapists should notify the authorized treating physician when 1) clinical findings suggest serious medical or psychological pathology, 2) reported activity limitations are not consistent with the diagnosis, or 3) symptoms are not improving subjectively or objectively after 4 weeks or resolving with interventions focused on normalizing body function. Various means can be used to measure the functional success of treatment; however, it appears that an increase of 5kg lifting or 7 points on the pain disability index may be useful.

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.

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F.12.a Activities of Daily Living (ADL)

Activities of Daily Living (ADL) are well-established interventions which involve instruction, active-assisted training, and/or adaptation of activities or equipment to improve a person's capacity in normal daily activities such as self-care, work re-integration training, homemaking, and driving.

- Time to produce effect: 4 to 5 treatments
- Frequency: 3 to 5 times per week
- Optimum duration: 4 to 6 weeks
- Maximum duration: 6 weeks

F.12.b Aquatic Therapy

Aquatic Therapy is a well-accepted treatment that consists of the therapeutic use of aquatic immersion for therapeutic exercise to promote strengthening, core stabilization, endurance, ROM, flexibility, body mechanics, and pain management. Aquatic therapy includes the implementation of active therapeutic procedures in a swimming or therapeutic pool. The water provides a buoyancy force that lessens the amount of force gravity applies to the body. The decreased gravity effect allows the patient to have a mechanical advantage and more likely have a successful trial of therapeutic exercise. The therapy may be indicated for individuals who:

- cannot tolerate active land-based or full-weight bearing therapeutic procedures;
- require increased support in the presence of proprioceptive deficit;
- are at risk of compression fracture due to decreased bone density;
- have symptoms that are exacerbated in a dry environment;
- would have a higher probability of meeting active therapeutic goals than in a dry environment.

The pool should be large enough to allow full extremity range of motion and fully erect posture. Aquatic vests, belts and other devices can be used to provide stability, balance, buoyancy, and resistance.

- Time to produce effect: 4 to 5 treatments
- Frequency: 3 to 5 times per week
- Optimum duration: 4 to 6 weeks
- Maximum duration: 8 weeks

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A self-directed program is recommended after the supervised aquatics program has been established. Best practice suggests that the patient be transitioned to a dry environment exercises which may or may not be self-directed, after 4 to 6 weeks unless vocation involves significant time in the water. The transition to dry land may evolve over the course of weeks.

F.12.c Back Schools

These usually consist of an educational and skills acquisition program, including exercises, in which all lessons are delivered to groups of participants and supervised by a paramedical therapist or medical specialist. There is some evidence of a modest benefit from adding a back school to other treatments such as NSAIDs, massage, transcutaneous electrical nerve stimulation (TENS), and other physical therapy modalities. When prescribed, back schools should be initiated in the early phases of treatment.

F.12.d Functional Activities

These are well-established interventions that involve the use of therapeutic activity to enhance mobility, body mechanics, employability, coordination, balance, and sensory motor integration.

- Time to Produce Effect: 4 to 5 treatments.
- Frequency: 3 to 5 times per week.
- Optimum Duration: 4 to 6 weeks.
- Maximum Duration: 6 weeks.

F.12.e Functional Electrical Stimulation

Functional Electrical Stimulation is an accepted treatment in which the application of electrical current elicits involuntary or assisted contractions of atrophied and/or impaired muscles. It may be indicated for muscle atrophy in the limbs due to a radiculopathy.

- Time to produce effect: 2 to 6 treatments
- Frequency: 3 times per week
- Optimum duration: 8 weeks.
- Maximum duration: 8 weeks. If beneficial, provide with home unit.

F.12.f Neuromuscular Re-education

It is the skilled application of exercise with manual, mechanical, or electrical facilitation to enhance strength; movement patterns; neuromuscular response; proprioception, kinesthetic sense, and coordination; and education of movement, balance, and posture. Indications include the need to promote neuromuscular responses through carefully timed proprioceptive stimuli, elicit and improve motor activity in patterns similar to normal neurologically developed

sequences, and improve neuromotor response with independent control. There are multiple types of neuromuscular education. Two specific types are described below.

Spinal Stabilization

Spinal Stabilization is a type of neuromuscular re-education. The goal of this therapeutic program is to facilitate the attainment and maintenance of the spine in its patient-specific neutral and anatomically correct position. The stabilization is dynamic, which allows whole body movements while maintaining a stabilized spine. Progression of the program includes controlled movement of the spine to approximate normal biomechanical motions. It is the ability to move and function normally through postures and activities without creating undue vertebral stress. There is good evidence that a program of motor control exercises emphasizing the transverse abdominis, multifidi, and possible diaphragm and pelvic floor muscles is at least as effective as general exercise and manual therapy and may be more effective.

Directional Preference

This involves testing directional preference and incorporating the findings into exercise programs, commonly used in McKenzie therapy. Directional preference relies on a technique which tests the patient for a particular direction or directions of motion which, on repetition, causes a centralization of pain toward the midline from pain which has peripheral components. It may be used for herniated discs and mechanical low back pain. There appears to be good interexaminer reliability within credentialed and diplomated therapists for classifying patients into main syndromes and subgroups. Most patients will be classified into the reducible derangement syndrome which relies on directional preference. There is good evidence that centralization is a favorable prognostic factor in low back pain with and without sciatica. Seven visits may provide sufficient information for this evaluation.

There is some evidence that the McKenzie approach provides similar outcomes in improving pain, disability and ability to carry out ‘work activities’ in comparison with cognitive behavioral therapy. There is good evidence that a 12 week course of McKenzie therapy is at least as effective as, and may have modestly superior results to, chiropractic manipulation in reducing disability from nonspecific low back pain lasting 6 weeks or more. There is some evidence that the McKenzie method is as effective as intensive dynamic strengthening training in reducing short-term back and leg pain intensity in nonspecific low back pain. The studies taken as a group provide good evidence in support of the McKenzie therapy for low back pain.

Patients with a directional preference should engage in exercise regimens emphasizing the preferred position(s)/posture(s)/plane(s) and receive the appropriate education to facilitate its usage across a spectrum of activities including those at work. Following documented improvement of at least two weeks, gentle exercises moving against the original plane (or planes) of directional preference should be initiated, but always followed by exercises in the direction of the directional preference. Progression to the movements necessary to successfully perform the specific tasks necessary to resume full duty labor should occur according to the tolerance of the patient.

Total Timeframes for all Neuromuscular Re-Education

- Time to Produce Effect: 4 to 8 treatments.
- Frequency: 3 to 5 times per week.
- Optimum Duration: 4 to 8 weeks.
- Maximum Duration: 8 weeks.

F.12.g Therapeutic Exercise

Therapeutic exercise with or without mechanical assistance or resistance may include the following: isoinertial, isotonic, isometric and isokinetic types of exercises. Indications include the need for cardiovascular fitness, reduced edema, improved muscle strength; improved connective tissue strength and integrity, increased bone density, promotion of circulation to enhance soft tissue healing, improvement of muscle recruitment, improved proprioception, and coordination, and increased range of motion.

There is some evidence that intensive exercise coupled with cognitive behavioral therapy (CBT) is as effective for chronic un-operated low back pain as posterolateral fusion.

There is good evidence that exercise alone or as part of a multi-disciplinary program results in decreased disability for workers with non-acute low back pain.

Therapeutic exercise programs should be specific to the injury and address general functional deficits as identified in the diagnosis and clinical assessment. Patients should be instructed in and receive a home exercise program that is progressed as their functional status improves. Upon discharge, the patient should be independent in the performance of the home exercise program and should have been educated in the importance of continuing such a program. Educational goals include the development of strategies to maintain or further improve function and to minimize the risk for aggravation of symptoms in the future.

For spinal stabilization or directional preference, McKenzie, refer to F.12.f. Neuromuscular Re-education.

- Time to produce effect: 2 to 6 treatments
- Frequency: 3 to 5 times per week
- Optimum duration: 4 to 8 weeks and concurrent with an active daily home exercise program.
- Maximum duration: 8 weeks of therapist oversight. Home exercise should continue indefinitely.

Other movement therapy which may be included in therapeutic exercise includes yoga and other alternative exercise therapy supervised by a physician or other appropriate health care professional. Yoga emphasizing structural alignment and postural tolerances is recommended for patients who prefer yoga. There is some evidence that Iyengar restorative yoga, which avoids back bending, results in improved function and decreased chronic mechanical low back pain.

There is some evidence that yoga emphasizing mobility, strength, and posture to relieve pain may be more effective than usual care for chronic and recurrent low back pain. There is strong evidence that yoga has small to moderate advantages over an educational booklet only in reducing low back pain and back specific disability but no evidence that yoga is superior to stretching and strengthening classes led by a physical therapist. The referring health care provider must assure that the instructor has been working with individuals with back pain and is aware of the diagnosis and any activity or positional intolerances. Yoga may be an option for motivated patients whose primary functional goal involves improving positional tolerances.

- Time to Produce Effect: 6 to 8 private or small group sessions.
- Frequency: 3 to 5 times per week with daily home practice.
- Optimum Duration: 6 to 8 weeks of classes and concurrent with an active daily home exercise program.
- Maximum Duration: 8 to 10 weeks of therapist oversight. Home exercise should continue indefinitely.

F.12.h Work Conditioning

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 neuro-musculoskeletal 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 modalities, both active and passive, in conjunction with therapeutic exercise, functional activities, general conditioning, body mechanics, and lifting techniques re-training.

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.

- Length of Visit: 1 to 2 hours per day.
- Frequency: 2 to 5 visits per week.
- Optimum Duration: 2 to 4 weeks.
- Maximum Duration: 6 weeks. Participation in a program beyond six weeks must be documented with respect to need and the ability to facilitate positive symptomatic or functional gains.

F.12.i 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 (FCE) and/or jobsite analysis.

- Length of Visit: 2 to 6 hours per day.
- Frequency: 2 to 5 visits per week.
- Optimum Duration: 2 to 4 weeks.
  Maximum Duration: 6 weeks. Participation in a program beyond 6 weeks must be documented with respect to need and the ability to facilitate positive symptomatic or functional gains

F.13 Therapy - Passive

Most of the following passive therapies and modalities are generally 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 and to improve the rate of healing soft tissue injuries. They should be used adjunctively with active therapies, such as postural stabilization and exercise programs to help control swelling, pain, and inflammation during the active rehabilitation process. Please refer to F.12 Therapy - Active. Passive therapies may be used intermittently as a therapist deems appropriate or regularly if there are specific goals with objectively measured functional improvements during treatment.

The following passive therapies are listed in alphabetical order:

F.13.a Electrical Stimulation (Unattended)

An accepted treatment. Once applied, unattended electrical stimulation requires minimal on-site supervision by the physical therapist, occupational therapist, or other provider. Indications include muscle spasm, atrophy, and the need for osteogenic stimulation. A home unit should be purchased if treatment is effective, and frequent use is recommended.

- Time to produce effect: 2 to 4 treatments
- Frequency: Varies, depending upon indication, between 2 to 3 times/day to 1 time/week. Home unit should be purchased if treatment is effective and frequent use is recommended.
- Optimum duration: 4 treatments for clinic use
- Maximum duration: 8 treatments for clinic use

F.13.b Iontophoresis

There is no proven benefit for this therapy in the low back. Not recommended due to lack of evidence in the lumbar spine.

F.13.c Low Level Laser

Low Level Laser is not recommended as there is no proven benefit for this intervention due to lack of studies of sufficient quality. There is not enough research at this time to support this modality in the treatment of lower back (lumbar) injuries. Results of Low Level Laser have been mixed and often of poor quality.

F.13.d Manipulation

Manipulative treatment (not therapy) is defined as the therapeutic application of manually guided forces by an operator to improve physiologic function and/or support homeostasis that has been altered by the injury or occupational disease and has associated clinical significance.

For acute low back pain, there is good evidence that manipulation does not have a clinically greater therapeutic effect on acute , 6 weeks or less, nonspecific low back pain than other interventions including physical therapy.

For subacute/chronic pain, there is some evidence that manipulation/mobilization, including thrust techniques, may provide additional benefits on pain and function when used to supplement an individually tailored exercise program. There is good evidence that two sessions of thrust manipulation of the thoracolumbar spine followed by an exercise regimen leads to better low back function at six months than oscillatory non-thrust manipulation in patients with subacute low back pain. The study found patients with the following characteristics were likely to benefit from the program: segmental hypomobility, no symptoms distal to the knee, low fear-avoidance scores, and preservation of at least 35 degrees of internal rotation in at least one hip.

There is some evidence that manual therapy, followed by active exercises, may be effective for the reduction of disability from nonspecific low back pain lasting more than 12 weeks.

There is good evidence that spinal manipulative therapy (SMT) is comparable to exercise, standard medical care, and physiotherapy in reducing chronic low back pain, and good evidence that that SMT does not provide a clinically important superior pain relief over these interventions.

The decision to refer a patient for spinal manipulation rather than for other treatments should be made on the basis of patient preference and relative safety, not on an expectation of a greater treatment effect. It may be the first line of treatment, in combination with active therapy for some patients and should strongly be considered for patients with positive provocative testing for SI joint dysfunction or facet dysfunction who are not recovering in the first few weeks. Manipulation may be indicated in patients who have not had an evaluation for manual medicine, or who have not progressed adequately in an exercise program.

Manipulative treatments may be applied by osteopathic physicians (D.O.), chiropractors (D.C.), properly trained physical therapists (P.T.), properly trained occupational therapists (O.T.), or

properly trained medical doctors (M.D.). Some popular and useful techniques include, but are not limited to, high velocity, low amplitude (HVLA), muscle energy (ME), strain-counterstrain, a balanced ligamentous tension (BLT) and myofascial release (MFR). Under these different types of manipulation exist many subsets of techniques that can be described as: (a) direct- a forceful engagement of a restrictive/pathologic barrier, (b) indirect- a gentle/non-forceful disengagement of a restrictive/pathologic barrier, (c) the patient actively assists in the treatment and (d) the patient relaxing, allowing the practitioner to move and balance the body tissues. When the proper diagnosis is made and coupled with the appropriate technique, manipulation has no contraindications and can be applied to all tissues of the body, including muscles, tendons, ligaments, joints, fascia, and viscera. Pre-treatment assessment should be performed as part of each manipulative treatment visit to ensure that the correct diagnosis and correct treatment are employed.

Contraindications to HVLA manipulation include joint instability, fractures, severe osteoporosis, infection, metastatic cancer, active inflammatory arthritides, aortic aneurysm, and signs of progressive neurologic deficits.

- Time to produce effect for all types of manipulative treatment: 4 to 6 treatments.
- Frequency: 1 to 2 times per week for the first 2 weeks as indicated by the severity of the condition. Treatment may continue at 1 treatment per week for the next 6 weeks.
- Optimum duration: 8 weeks
- Maximum duration: 8 weeks. At week 8, patients should be re-evaluated. Care beyond 8 weeks may be indicated for certain chronic pain patients in whom manipulation is helpful in improving function, decreasing pain, and improving quality of life. In these cases, treatment may be continued at one treatment every other week until the patient has reached MMI and maintenance treatments have been determined. Extended durations of care beyond what is considered “maximum” may be necessary in cases of re-injury, interrupted continuity of care, exacerbation of symptoms, and in those patients with co-morbidities. Such care should be re-evaluated and documented on a monthly basis.

F.13.e Manipulation under General Anesthesia (MUA)

Manipulation under General Anesthesia (MUA) refers to manual manipulation of the lumbar spine in combination with the use of a general anesthetic or conscious sedation. It is intended to improve the success of manipulation when pain, muscle spasm, guarding, and fibrosis appear to be limiting its application in patients otherwise suitable for their use. There have been no high-quality studies to justify its benefits given the risks of general anesthetic and conscious sedation. It is not recommended.

F.13.f Manipulation under Joint Anesthesia (MUJA)

Manipulation under Joint Anesthesia (MUJA) refers to manipulation of the lumbar spine in combination with a fluoroscopically guided injection of anesthetic with or without corticosteroid agents into the facet joint at the level being manipulated. There are no controlled clinical trials to support its use. It is not recommended.

F.13.g Massage - Manual or Mechanical

Massage - Manual or Mechanical Massage is manipulation of soft tissue with broad ranging relaxation and circulatory benefits. This may include stimulation of acupuncture points and acupuncture channels (acupressure), application of suction cups, and techniques that include pressing, lifting, rubbing, pinching of soft tissues by or with the practitioners' hands. Indications include edema (peripheral or hard and non-pliable edema), muscle spasm, adhesions, the need to improve peripheral circulation and ROM, or the need to increase muscle relaxation and flexibility prior to exercise.

There is good evidence that massage therapy in combination with exercise reduces pain and improves function short-term for patients with sub-acute low back pain. There is some evidence that massage may be beneficial for low back pain, especially when combined with exercise. It is required that all massage be performed by trained, experienced therapists, overseen and evaluated by the authorized treating physician and best practice suggests that the modality is accompanied by an active exercise program and patient education. In contrast to the sub-acute population, massage is a generally accepted treatment for the acute low back pain population, although no studies have demonstrated its efficacy for this set of patients.

- Time to produce effect: Immediate
- Frequency: 1 to 2 times per week
- Optimum duration: 6 weeks
- Maximum duration: 2 months

F.13.h Mobilization (Joint)

Mobilization (Joint) is is a passive movement involving oscillatory motions to the vertebral segment(s). The passive mobility is performed in a graded manner (I, II, III, IV, or V), which depicts the speed and depth of joint motion during the maneuver.

For acute low back pain, there is good evidence that manipulation does not have a clinically greater therapeutic effect on acute, 6 weeks or less, nonspecific low back pain than other interventions including physical therapy.

For subacute/chronic pain, there is some evidence that manipulation/mobilization, including thrust techniques, may provide additional benefits on pain and function when used to supplement an individually tailored exercise program. There is good evidence that two sessions of thrust manipulation of the thoracolumbar spine followed by an exercise regimen leads to better low back function at six months than oscillatory non-thrust manipulation in patients with subacute low back pain. The study found patients with the following characteristics were likely to benefit

from the program: segmental hypomobility, no symptoms distal to the knee, low fear-avoidance scores, and preservation of at least 35 degrees of internal rotation in at least one hip.

There is some evidence that manual therapy, followed by active exercises, may be effective for the reduction of disability from nonspecific low back pain lasting more than 12 weeks.

There is good evidence that spinal manipulative therapy (SMT) is comparable to exercise, standard medical care, and physiotherapy in reducing chronic low back pain, and good evidence that that SMT does not provide a clinically important superior pain relief over these interventions.

There is some evidence that a 2 day course focusing on the biopsychosocial model with an emphasis on the goals of returning to usual activities and fitness is as effective in reducing disability as six sessions of manual therapy sessions provided by physiotherapists and more limited patient education.

For further discussion on grade V joint mobilization, please see the section on high velocity low amplitude (HVLA) manipulation (refer to F.13.d. Manipulation). It may include skilled manual joint tissue stretching. Indications include the need to improve joint play, segmental alignment, and intracapsular arthrokinematics, or the need to reduce pain associated with tissue impingement. Mobilization should be accompanied by active therapy.

Grade V mobilization contraindications include joint instability, fractures, severe osteoporosis, infection, metastatic cancer, active inflammatory arthritides, aortic aneurysm, and signs of progressive neurologic deficits.

- Time to produce effect: 6 to 9 treatments
- Frequency: Up to 3 times per week
- Optimum duration: 4 to 6 weeks
- Maximum duration: 6 weeks

F.13.i Mobilization (Soft Tissue)

Mobilization (Soft Tissue) is agenerally well-accepted treatment. Mobilization of soft tissue is the skilled application of muscle energy, strain/counter strain, myofascial release, manual trigger point release, and manual therapy techniques designed to improve or normalize movement patterns through the reduction of soft tissue pain and restrictions. These can be interactive with the patient participating or can be with the patient relaxing and letting the practitioner move the body tissues. Indications include muscle spasm around a joint, trigger points, adhesions, and neural compression. Best practice suggests that mobilization should be accompanied by active therapy.

- Time to produce effect: 4 to 9 treatments
- Frequency: Up to 3 times per week
- Optimum duration: 4 to 6 weeks

- Maximum duration: 6 weeks

F.13.j Short-Wave Diathermy

Short-Wave Diathermy is an accepted treatment that involves the use of equipment that exposes soft tissue to a magnetic or electrical field. Indications include enhanced collagen extensibility before stretching, reduced muscle guarding, reduced inflammatory response, and enhanced re-absorption of hemorrhage/hematoma or edema. Best practice suggests that this modality be accompanied by active therapy.

- Time to produce effect: 2 to 4 treatments
- Frequency: 2 to 3 times per week up to 3 weeks
- Optimum duration: 3 to 5 weeks
- Maximum duration: 5 weeks

F.13.k Superficial Heat and Cold Therapy (excluding Infrared Therapy)

Superficial Heat and Cold Therapy (excluding Infrared Therapy) is a generally accepted treatment. Superficial heat and cold are thermal agents applied in various manners that lower or raise the body tissue temperature for the reduction of pain, inflammation, and/or effusion resulting from injury or induced by exercise. Includes application of heat just above the surface of the skin at acupuncture points. Indications include acute pain, the need to increase pain threshold, the need to reduce muscle spasm, and the need to promote stretching/flexibility. Cold and heat packs can be used at home as an extension of therapy in the clinic setting.

- Time to produce effect: Immediate
- Frequency: 2 to 5 times per week
- Optimum duration: 3 weeks as primary or intermittently as an adjunct to other therapeutic procedures up to 2 months
- Maximum duration: 2 months

F.13.l Traction - Manual

Traction—Manual is an accepted treatment and an integral part of manual manipulation or joint mobilization. Indications include decreased joint space, muscle spasm around joints, and the need for increased synovial nutrition and response. Manual traction is contraindicated in patients with tumor, infection, fracture, or fracture dislocation. Best practice suggests that this modality be accompanied by active therapy.

- Time to produce effect: 1 to 3 sessions
- Frequency: 2 to 3 times per week
- Optimum duration: 30 days
- Maximum duration: 1 month

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F.13.m Traction - Mechanical

There is good evidence that mechanical traction is not useful for low back pain patients with sciatica nor those with low back pain without radicular symptoms. Therefore, it is not recommended in this population.

F.13.n Transcutaneous Electrical Nerve Stimulation (TENS)

Transcutaneous Electrical Nerve Stimulation (TENS) is interferential squared wave with microcurrent, usually with four channels. A generally accepted treatment. TENS should include at least one instructional session for proper application and home use. Indications include muscle spasm, atrophy, and decreased circulation and pain control. Minimal TENS unit parameters should include pulse rate, pulse width, and amplitude modulation. Consistent, measurable functional improvement must be documented prior to the purchase of a home unit.

- Time to produce effect: Immediate
- Frequency: Variable
- Optimum duration: 3 sessions
- Maximum duration: 3 sessions. If beneficial, provide with home unit or purchase if effective

F.13.o Ultrasound (Including Phonophoresis)

There is no proven benefit for this therapy in the low back. Not recommended due to lack of evidence in the lumbar spine

F.13.p Vertebral Axial Decompression (VAX-D)/DRX, 9000

Motorized traction devices that purport to produce non-surgical disc decompression by creating negative intradiscal pressure in the disc space; included are devices with the trade names VAX-D and DRX 9000. There are no quality randomized studies to support their use. They are not recommended. A report of a case in which a herniated disc progressed while using VAX D is of some concern. The proposed mechanism involves some active back muscle response which can be created by passive traction and may increase disc pressure.

F.14 Vocational Rehabilitation

Vocational Rehabilitation is a generally accepted intervention. Initiation of vocational rehabilitation requires adequate evaluation of patients for quantification of highest functional level, motivation, and achievement of MMI. Vocational rehabilitation may be as simple as returning to the original job or as complicated as being retrained for a new occupation.

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

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and direction may aid the patient in decreasing stress and depression and promote optimum rehabilitation.

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G. Therapeutic Procedures - Operative

In order to justify operative interventions, clinical findings, clinical course and diagnostic tests must all be consistent resulting in a reasonable likelihood of at least a measurable and meaningful functional and symptomatic improvement. A comprehensive assimilation of these factors must lead to a specific diagnosis with positive identification of pathologic conditions and in most cases a specific site of nerve root compression, spinal cord compression, or spinal instability. It is imperative to rule out non-physiologic modifiers of pain presentation or non-operative conditions mimicking radiculopathy or instability (e.g., psychological conditions, peripheral neuropathy, myofascial pain, rheumatologic, or other pain syndromes, etc.) prior to consideration of elective surgical intervention.

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 neuro-musculoskeletal examination to identify mechanical pain generators that may respond to non-surgical techniques or may be refractory to surgical intervention. Patients who demonstrate centralization on directional preference testing may not need surgery when treated with directional preference neuromuscular educations. Refer to F.12.g Therapeutic Exercise.

While sufficient time allowances for non-operative treatment are required to determine the natural cause and response to non-operative treatment of lumbar pain disorders, an accurate diagnosis and timely decision making for operative intervention are critical. Thorough neurologic exams should be performed periodically to assure timely treatment; to avoid de-conditioning and increased disability; and to treat emergent pathology or neurologically compromising conditions which may require early surgery**.**

Brief psychological screening tools, or more frequently full evaluations, are done to predict surgical success. Psychological screening is indicated for all patients with continuing pain who are considering surgical interventions. Lower patient satisfaction after repeat surgical procedures and other treatment are related to pre-existing depression.

In general, if the program of non-operative treatment fails, operative treatment is indicated when symptoms and findings suggest a surgically amenable problem and:

- Improvement of the symptoms has plateaued and the residual symptoms of pain and functional disability are unacceptable at the end of 6 to 12 weeks of active therapy and manual treatment (mere passage of time with poorly guided treatment is not considered an active treatment program). In cases of myelopathy and some cases of severe nerve root compression, earlier intervention is indicated; or

- Frequent recurrences of symptoms cause serious functional limitations, even if a non-operative active treatment program provides significant improvement of symptoms, and restoration of function on each recurrence; and

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- The patient and treating physician have identified functional operative goals and the likelihood of achieving improved ability to perform activities of daily living or work activities. The patient should agree to comply with the pre- and post-operative treatment plan including home exercise. The provider should be especially careful to make sure the patient understands the amount of post-operative treatment required and the length of partial- and full-disability expected post-operatively. The patient should have committed to the recommended post-operative treatment plan and fully completed the recommended active, manual and pre-operative treatment plans.

There are some clinical scenarios which necessitate surgical interventions. Surgical workup and implementation of decompression of patients with herniated nucleus pulposus and radiculopathy should occur within six to twelve weeks, at the latest, after injury within the above stated contingencies. Small herniations and most protrusions are often not pain generators, however small foraminal disc herniations are likely to compress the nerve root and may require surgical removal.

In order to qualify for surgery for nerve root compression, the patient should exhibit the following signs of radiculopathy before invasive procedures are considered:

- pain in the legs greater than in the low back which interferes with function, return to work and/or active therapy; and

- physical exam findings of abnormal reflexes, motor weakness or radicular sensation deficits; and

- findings on the MRI which indicate impingement of nerves or the spinal cord corresponding to reproducible physical exam findings.

Treatment of myelopathy may occur earlier. Surgical procedures should be directed toward neurological findings which correlate with MRI imaging. For the unusual patients with refractory lumbar pain in whom fusion is being considered, it is strongly recommended that a decisive commitment to surgical or non-surgical interventions occur within five months following injury.

Re-operation is indicated only when the functional outcome following the re-operation is expected to be better, within a reasonable degree of certainty, than the outcome of other non-invasive or less invasive treatment procedures. “Functional outcomes” refer to the patient’s ability to improve functional tolerances such as, standing, walking, strength, endurance, functional lumbar range of motion, and/or vocational status. While timely surgical decision-making is critical to avoid de-conditioning and increased disability, a time limited trial of reconditioning should be tried prior to re-operation. Re-operation has a high rate of complications and failure and may lead to disproportionately increased disability.

Every post-operative patient should be involved in an active treatment program after clearance by the surgeon (refer to F.12. Therapy – Active). Interdisciplinary interventions should be

strongly considered post-operatively in any patient not making functional progress within expected timeframes (refer to F.6 Interdisciplinary Rehabilitation Programs).

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. Since most patients with the most common conditions will improve significantly over time, without invasive interventions, patients must be able to make well-informed decisions regarding their treatment.

Return to work restrictions should be specific according to the recommendations in Section F.11. Return to Work. Most surgical patients can return to a limited level of duty between three to six weeks. Full activity is generally achieved between three months to one year, depending on the procedure, the type of duties performed, and healing of the individual. Patients should be informed of expected time off work.

G.1 Discectomy (Usually Accompanied by Partial Laminectomy)

Description
To enter into and partially remove the disc. May be an open procedure or minimally invasive, and usually involves partial laminectomy.

Complications
Include, but are not limited to, nerve damage, spinal fluid leakage, infection, and hemorrhage.

Surgical Indications
To include all of the following: specific diagnosis of nerve root compression proven by MRI or CT myelogram and correlated to exam findings, primary radicular symptoms, radiculopathy on exam (Refer to beginning of this section G. for a description of radiculopathy) and failure of 6 weeks of active therapy. In some cases, surgery may need to occur sooner due to an individual's inability to participate in active therapy. Epidural injections have not been proven to have long-term benefit; however they may be trialed prior to surgery if the patient wishes to try to avoid surgery or is unable to participate in therapy after the first 2 weeks.

There is good evidence that after 6 weeks of active therapy, those patients with persistent radicular leg pain and an image-confirmed disc herniation have better functional outcomes than non-operated patients. This outcome is more likely to be observed within the first 2-3 months after surgery. However non-operative groups also improved significantly over 2 years.

The purpose of spinal injections, as well as surgery, is to facilitate active therapy by providing short-term relief through reduction of pain. Since most patients with these conditions will improve significantly over time, without invasive interventions, patients must be able to make well-informed decisions regarding their treatment.

Operative Treatment
Partial discectomy and root decompression.

Post-Operative Therapy
An individualized rehabilitation program based upon communication between the surgeon and the therapist and using the therapies as outlined in Section F. Therapeutic Procedures Non-Operative. In all cases, communication between the physician and therapist is important to the timing of exercise progressions. Post-operative active treatment will frequently require a repeat of the therapy sessions previously ordered. The implementation of a gentle aerobic reconditioning program (e.g., walking) and back education within the first post-operative week is appropriate in uncomplicated post-surgical cases. Some patients may benefit from several occupational therapy visits to improve performance of ADLs. Participation in an active therapy program which includes restoration of ROM, core stabilization, strengthening, and endurance is often recommended to be initiated three to twelve weeks post-operatively. The goals of the therapy program should include instruction in a long-term home based exercise program (refer to F.12. Therapy – Active). Medium or heavy lifting should not be begun before 10 to 12 weeks in most cases.

G.2 Percutaneous Discectomy

Description
An invasive operative procedure to accomplish partial removal of the disc through a needle which allows aspiration of a portion of the disc trocar under imaging control.

Complications
Include, but are not limited to, injuries to the nerve or vessel, infection, hematoma, and incomplete nerve root decompression.

Surgical Indications
Percutaneous discectomy is indicated only in cases of suspected septic discitis in order to obtain diagnostic tissue. The procedure is not recommended for contained disc herniations or bulges with associated radiculopathy due to lack of evidence to support long-term improvement.

G.3 Laminotomy/Laminectomy/Foramenotomy/Facetectomy for Central or Lateral Spinal Stenosis

Description
These procedures provide access to produce neural decompression by partial or total removal of various parts of spinous elements.

Complications
Include, but are not limited to, nerve injury, post-surgical instability, cerebrospinal fluid (CSF) leakage, hematoma, infection, and incomplete decompression.

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Surgical Indications
Include all of the following:

- Radicular symptoms or symptoms of neurogenic claudication, often with clinical evidence of radiculopathy that correlates with the patient's pain and findings.

- Evidence of nerve root compression generally proven by MRI or CT myelogram.

- Failure of non-surgical care. For patients with stenosis non-surgical active treatment should generally consist of 6 to 12 weeks for an adequate trial. Patients with severe stenosis that correlates with symptoms often do not improve with conservative care.

There is good evidence that surgical treatment leads to better symptomatic and functional outcomes however those with non-surgical treatment may also improve slightly. The non-operative improvement appears to be less likely for stenosis than for herniated discs. In the randomized spinal stenosis trial with cross over, 1/3 of those in the surgery group did not have surgery and about 40% of those in the non-surgical group eventually had surgery.

The purpose of spinal injections, as well as surgery, is to facilitate active therapy by providing short-term relief through reduction of pain. Since most patients with these conditions will improve significantly over time, without invasive interventions, patients must be able to make well-informed decisions regarding their treatment.

Operative Treatment
Laminotomy, laminectomy root decompression, and excision of synovial cyst.

Post-Operative Therapy
An individualized rehabilitation program based upon communication between the surgeon and the therapist and using the therapies as outlined in Section F. Therapeutic Procedures Non-Operative. In all cases, communication between the physician and therapist is important to the timing of exercise progressions. Post-operative active treatment will frequently require a repeat of the therapy sessions previously ordered. The implementation of a gentle aerobic reconditioning program (e.g., walking) and back education within the first post-operative week is appropriate in uncomplicated post-surgical cases. Some patients may benefit from several occupational therapy visits to improve performance of ADLs. Participation in an active therapy program which includes restoration of ROM, core stabilization, strengthening, and endurance is often recommended to be initiated three to twelve weeks post-operatively. The goals of the therapy program should include instruction in a long-term home based exercise program (refer to F.12. Therapy – Active). Medium or heavy lifting should not be begun before 10 to 12 weeks in most cases.

G.4 Spinal Fusion (Usually Combined with Decompression)

Description
Use of bone grafts, sometimes combined with instrumentation, to produce a rigid connection between two or more adjacent vertebrae.

Complications
Complications include instrumentation failure, bone graft donor site pain, superficial infection, deep wound infection, and graft extrusion. There is an increased likelihood of complications with instrumented fusion, although the majority of them are minor. There is some evidence that morbid obesity increases hospital length of stay, mortality and postoperative complications of spinal fusion surgery and results in concomittant increases in cost. Fusion can accelerate adjacent level disease. In one study, more than 1/3 of patients required surgery at an adjacent level by ten years. Refer to the following recombinant human bone morphogenetic protein section for complications from their use.

Surgical Indications
A timely decision-making process is recommended when considering patients for possible fusion. The treatment for some patients with lumbar fractures may be immediate fusion. For chronic low back problems, fusion should not be performed within the first five months of symptoms, except for fracture, dislocation, or for some patients with functional loss due to stenosis and instability.

One study of lumbar fusion outcomes in a population of workers compensation patients showed that complications occurred in 36% of patients with a 26% reoperation rate. Only 26% of patients returned to work while 67% of non-operated case returned to work however, it is not clear that severity was fully controlled for. Of the patients with lumbar fusion the following predicted non-return to work: daily morphine usage above 25 MEQ 90 days post-surgery, reoperation, complications from surgery, and days off work prior to surgery. Another study of workers compensation patients and others on government funded programs (Social Security Disability Insurance (SSDI), Medicaid and Medicare age below 50 years) found that workers compensation (WC) patients continued to have significantly less benefit for relief of leg and back pain and lesser benefits on the Oswestry Disability Index than other patients, both controls and others on government programs. The American Pain Society Guidelines note that less than half of patients with degenerative changes treated by fusion experience no pain or only sporadic pain, only a slight restriction in function and occasional use of analgesics. Fusion outcomes are better for those with symptomatic stenosis and instability.

There is good evidence that decompression and fusion, with or without instrumentation, of lumbar stenosis with degenerative spondylolisthesis leads to better 2 year outcomes for patients whose symptoms are severe. However, patients who choose non-operative treatment can also expect their symptoms to improve with nonsurgical treatment, and non-operative treatment is acceptable if this is the patient preference. Physicians should consider this when advocating for surgical procedures in this population. To assure better outcomes fusions should only be

performed on those who meet the indications below.

There is some evidence that provocative discography, facet joint blocks and temporary external transpedicular fixation do not adequately screen patients with nonspecific low back pain for fusion success. The tests tend to be sensitive but not specific.

In early studies of patients with spondylolisthesis undergoing decompression with or without instrumentation the relationship between a solid radiographic fusion and a good clinical outcome was not apparent. However, a later follow-up of the same population showed that 86% of the patients with a solid fusion had good to excellent clinical outcomes, compared to only 56% of patients who had a pseudarthrosis. There remains uncertainty concerning the optimal imaging method to detect a pseudarthrosis, with controversy about the amount of motion on flexion-extension films which indicate that a solid fusion has been achieved, and whether the information to be gained from a thin-cut CT justifies the radiation dose associated with that form of imaging. This guideline does not make a recommendation on the clinical significance of fusion detected by any form of imaging.

There is some evidence that fusion is likely to have a higher beneficial effect compared to multidisciplinary rehabilitation for patients with isthmic spondylolisthesis, as differentiated from those without the condition who suffered from chronic low back pain.

There is good evidence that intensive exercise for approximately 25 hours per week for four weeks, combined with cognitive interventions emphasizing the benefits of maintaining usual activity, produces functional results similar to those of posterolateral fusion in patients with chronic non-radicular back pain and no stenosis or instability after one year. This population may not reflect the workers compensation population as there is frequently little access to intensive rehabilitation programs. There is some evidence that lumbar fusion produces better symptomatic and functional results in patients with chronic non-radicular pain when several months of conservative treatment have not produced a satisfactory outcome. This population may better reflect the injured worker in Montana. Fusions associated with decompression are more likely to reduce leg pain in the presence of stenosis.

The effect of comorbidities on surgical outcomes should be considered and discussed with the patient before proceeding with complex spinal surgery. There is some evidence that morbid obesity increases hospital length of stay, mortality, and postoperative complications after spinal fusion surgery, with concomitant increases in hospital costs. Another similar study did not find increased hospital stays but did show an increased cost and higher rates of non-routine discharges and transfusions for obese and morbidly obese patients. A third study of spinal fusion and metabolic syndrome found higher hospital charges, higher rates of non-routine discharges and increased rates of major life-threatening complications.

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. The purpose of spinal injections, as well as

surgery, is to facilitate active therapy by providing short-term relief through reduction of pain. Since most patients with these conditions will improve significantly over time, without invasive interventions, patients must be able to make well-informed decisions regarding their treatment.

Use Recombinant Human Bone Morphogenetic Protein (rhBMP-2) in fusions**:** A member of a family of cytokines capable of inducing bone formation. It is produced from genetically modified cell lines using molecular cloning techniques. At the time of this guideline revision, rhBMP-2 is FDA approved for use in anterior lumbar interbody fusion (ALIF) at one level from L4-S1 in a skeletally mature patient and is used with a carrier, such as a collagen sponge or other matrix, and a cage. There is some evidence that anterior interbody cage fusion using rhBMP-2 results in shorter operative time compared with the use of iliac crest bone autograft. Minor pain at the iliac crest donor site may persist for 24 months or longer in approximately 30% of patients who undergo an autograft procedure, although local bone graft can also be used for single level fusions. RhBMP-2 avoids the need for harvesting iliac crest donor bone and can therefore, avoid this complication of persistent pain. Despite this, there is good evidence that rhBMP has no clinically important advantage over bone graft for anterior lumbar interbody fusion or posterior lumbar fusion.

There is a potential for patients to develop sensitizing or blocking antibodies to rhBMP-2 or to the absorbable collagen sponge. The long-term effects are unknown. The rhBMP-2 used with the interbody fusion device is contraindicated for patients with a known hypersensitivity to Recombinant Human Bone Morphogenetic Protein -2, bovine type 1 collagen, or to other components of the formulation. Use of rhBMP-2 outside the anterior cage may carry a risk of swelling and ectopic bone formation, which can encroach on neurovascular structures. One study noted a higher incidence of retrograde ejaculation in ALIF cases using rhBMP-2.

One study has reported increased neurological compromise when rhBMP was used for posterior interbody fusion or transforaminal lumbar interbody fusion. Another systematic review of rhBMP for posterior interbody fusions, posterior lumbar interbody fusion and transforaminal lumbar interbody fusion, noted appreciable rates of complications including heterotopic ossification within the epidural space or neuroforamina, postoperative radiculitis and endplate osteolyosis with interbody subsidence. At the time of this guideline revision, it is still not FDA approved for posterior interbody fusion use and considered investigational. These results should be considered prior to its use. Generally **not recommended** but off-label use on a case by case basis with prior authorization may be considered.

There is insufficient information to form a recommendation with instrumentation other than the cage specifically designed for anterior procedures. If the FDA approves its use for other operative approaches, prior authorization is required. Off label use may be considered on a case by case basis. The patient must meet all indications on the device manufacturer's list and have no contraindications. The formation of exuberant or ectopic

bone growth at the upper levels (L_2–L_4) may have a deleterious impact on certain neurovascular structures, such as the aorta and sympathetic nerve chain. There are also reports of osteoclastic activity with the use of rhBMP-2. One follow-up study noted bone resorption after transforaminal lumbar interbody fusion with rhBMP-2 at a moderate or severe level in 49% of patients treated with or without a cage. This can also result in worsening back pain in the first 3 months after the procedure. However early osteolyosis can resolve.

The patient must meet all indications of the device manufacturer's list and have no contraindications.

Diagnostic Indications

Indications for spinal fusion may include:

1. Neural arch defect usually with stenosis or instability – Spondylolytic spondylolisthesis, congenital unilateral neural arch hypoplasia. It should be noted that the highest level of success for spinal fusions is when spondylolisthesis grade 2 or higher is present.

2. Segmental Instability - Excessive motion, as in degenerative spondylolisthesis 4mm or greater, surgically induced segmental instability.

3. Primary Mechanical Back Pain/Functional Spinal Unit Failure - Multiple pain generators objectively involving two or more of the following: (a) internal disc disruption (poor success rate if more than one disc involved), (b) painful motion segment, as in annular tears, (c) disc resorption, (d) facet syndrome, and/or (e) ligamentous tear. Because surgical outcomes are less successful when there is neither stenosis nor instability, the requirements for pre-operative indications must be strictly adhered to for this category of patients.

4. Revision surgery for failed previous operation(s) if significant functional gains are anticipated.

5. Other diagnoses: Infection, tumor, or deformity of the lumbosacral spine that cause intractable pain, neurological deficit, and/or functional disability.

Pre-operative Surgical Indications

Required pre-operative clinical surgical indications for spinal fusion include all of the following:

1. All pain generators are adequately defined and treated; and

2. All physical medicine and manual therapy interventions are completed; and

3. X-ray, MRI, or CT myelography demonstrate spinal stenosis with instability or disc pathology, requiring decompression that may surgically induce segmental instability or a positive discogram; and

4. Spine pathology is limited to two levels; and

5. Psychosocial evaluation with confounding issues addressed; (required for all cases except those with degenerative spondylolisthesis with persistent claudication or radicular leg pain with neurologic signs); and

6. For any potential fusion surgery, it is recommended that the injured worker refrain from smoking for at least six weeks prior to surgery and during the period of fusion healing. Because smokers have a higher risk of non-union and higher post-operative costs, it is recommended that insurers cover a smoking cessation program peri-operatively.

Operative Treatment

Operative procedures may include: (a) Intertransverse fusion often with pedicle screws; (b) Anterior fusion (with or without rhBMP-2) – generally used for component of discogenic pain where there is no significant radicular component requiring decompression; (c) Posterior interbody fusion – generally used for component of discogenic pain where posterior decompression for radicular symptoms is also performed; or (d) Anterior/posterior (360°) fusion – most commonly seen in unstable or potentially unstable situations or non-union of a previous fusion. Iliac crest bone grafts do not appear to result in increased complications, reoperation or patient dissatisfaction.

Post-operative Therapy

An individualized rehabilitation program based upon communication between the surgeon and the therapist and using the therapies as outlined in Section F. Therapeutic Procedures Non-Operative. In all cases, communication between the physician and therapist is important to the timing of exercise progressions. There is some evidence that it is appropriate to defer active rehabilitation until 12 weeks as groups beginning at 6 weeks had worse outcomes. Post-operative active treatment will frequently require a repeat of the therapy sessions previously ordered. The implementation of a gentle aerobic reconditioning program (e.g., walking), and back education within the first post-operative week is appropriate in uncomplicated post-surgical cases. Some patients may benefit from several occupational therapy visits to improve performance of ADLs. Participation in an active therapy program that includes core stabilization, strengthening, and endurance is recommended to be initiated once the fusion is solid and without complication. If it is performed, care should be taken not to overly mobilize the section above and below the fusion at that time. The goals of the therapy program should include instruction in a long-term home based exercise program (refer to F.12. Therapy – Active).

Return to work

Barring complications, patients responding favorably to spinal fusion may be able to

- Return to sedentary-to-light work within 6 to 12 weeks post-operatively; and

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- Perform light-to-medium work within 6 to 9 months post-operatively; and
- Perform medium-to-medium/heavy work within 6 to 12 months post-operatively.
- Heavy-to-very-heavy post-operative labor should be considered for vocational assessment as soon as reasonable restrictions can be restricted.

The practitioner should release the patient with specific physical restrictions and should obtain a clear job description from the employer if necessary. Once an injured worker is off work greater than six months, the functional prognosis with or without fusion becomes guarded for that individual.

G.5 Dynamic Neutralization System

A possible option to spinal fusion for patients with Grade 1 instability and symptomatic stenosis is a currently available in a posterior stabilization system device. This device attaches with pedicle screws and intends to address instability while allowing some segmental motion. It is expected to protect adjacent disc levels from the deterioration experienced with a complete fusion. It is also thought to provide a less invasive, less risky surgical procedure for patients with degenerative disc disease and functionally impairing pain with instability and stenosis. The FDA has not fully approved this system for this indication. Some case series of patients with stenosis and grade 1 instability have indicated less operating time, more rapid return to function and a slightly better outcome than those who received decompression and fusion. At this time the procedure is not recommended. Further studies may provide more conclusive information. If it is being considered the patient should not have osteoporosis and must meet all of the indications for fusion at one or two levels, including prior authorization. They should also have predominant leg pain over back pain.

G.6 Sacroliac Joint Fusion

Description
Use of bone grafts, sometimes combined with instrumentation.

Complications
Instrumentation failure, bone graft donor site pain, in-hospital mortality, deep infection, superficial infection, and graft extrusion.

Surgical Indications
Sacroiliac (SI) joint fusion may be indicated for stabilization of a traumatic severe disruption of the pelvic ring. This procedure has limited use in minor trauma and would be considered only on an individual case-by-case basis. In patients with typical mechanical low back pain, this procedure is considered to be investigational. Until the efficacy of this procedure for mechanical low back pain is determined by an independent valid prospective outcome study, this procedure is not recommended for mechanical low back pain.

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G.7 Implantable Spinal Cord Stimulators

Reserved for those low back pain patients with pain, radiculopathy, and failed surgery of greater than six months duration who have not responded to the standard non-operative or operative interventions previous discussed within this document. Refer to the Department's Chronic Pain Guideline.

G.8 Intradiscal Electrothermal Annuloplasty (IDEA) (More Commonly Called IDET, or Intradiscal Electrothermal Therapy)

IDET is an outpatient procedure. A wire is guided into the identified painful disc using fluoroscopy. The wire is then heated at the nuclear annular junction within the disc. Due to lack of evidence indicating benefit from this procedure, it is not recommended.

G.9 Interspinal Spacers

Description
Multiple interspinous spacer devices (IFDs) have been utilized to treat older patients (age 50 and over) with lumbar spinal stenosis (LSS) and intermittent neurogenic claudication (INC) Interspinous process decompression theoretically relieves narrowing of the spinal canal and neural foramen in extension, thereby reducing the symptoms of INC, secondary to LSS.

Complications
Complications include, but are not limited to, symptomatic spinous process fractures, new radicular defects, recurrent back pain, device extrusion, device failure with need for further surgery, and bilateral foot drop.

Surgical Indications
The device is indicated for treatment of patients 50 or older suffering from neurogenic intermittent claudication caused by lumbar spinal stenosis (with X-ray, MRI and/or CT evidence of thickened flavum, narrowed lateral recess and/or central canal narrowing).

There is some evidence that X-STOP spacer (a type of spacer devise) is superior to continuing nonoperative treatment after 6 months of conservative care has not resolved neurogenic claudication. However, one of the most recent studies found that within up to four postoperative years the complication rate was as high as 38%, with up to an 85% reoperation rate, and up to a 77% incidence of poor outcomes. Therefore, utilization and implantation of IFD remains extremely controversial and strict adherence to the indications is recommended. Only patients who meet the following should be considered:

- All pain generators are adequately defined and treated; and
- All physical medicine and manual therapy interventions are completed over 6 months; and

- Impaired physical function correlated with physical findings; and
- CT or MRI that demonstrates stenosis; and
- Spine pathology is limited to one or two levels; and
- Psychological evaluation to identify barriers to recovery; and
- It is recommended that the injured worker refrain from smoking for at least six weeks prior to surgery and during the period of healing.

Additionally, the candidate should meet the following criteria:

- 50 years or older; and
- Sit for 50 minutes without pain; and
- Walk up to 50 feet or more; and
- Relief in flexion from their symptoms of leg/buttock/groin pain, with or without back pain.

Contraindications

- Anatomy that prevents implantation due to significant lumbar instability, ankylosis, acute fracture of the spinous process or pars interarticularis
- Allergy to titanium or titanium alloy
- Significant scoliosis
- Fixed motor deficit
- Cauda equina syndrome
- Neural compression causing neurogenic bowel or bladder disfunction
- Previous lumbar surgery
- Significant peripheral neuropathy
- Spondylolisthesis greater than 1.0 (on a scale from 1-4) at the affected level
- Sustained pathological fractures

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- Severe osteoporosis of the vertebrae or hips
- Severe foraminal stenosis
- Obesity
- Active infection or systemic disease
- Paget's disease or metastasis to the vertebrae
- Steroid use for more than 1 month with 12 months preceding surgery
- Relative contraindication: adjacent level disease

Operative Treatment

Patients are placed on a radiolucent table in the right lateral decubitus position and asked to flex their spine. After the correct operative levels are confirmed through fluoroscopy, patients receive a local anesthetic. General anesthesia is typically not required. A mid-sagittal incision of approximately 4 cm is made over the spinous process of the stenotic level(s) and the musculature is elevated to the level of the lamina and facets. Occasionally, hypertrophied facets that are blocking entry to the anterior Interspinous space can be partially trimmed to enable anterior placement of the implant. A curved dilator is then inserted into the anterior margin of the interspinous space to pierce the Interspinous ligament. A sizing distractor is then inserted to determine the appropriate implant size. The spacer is then secured to the insertion instrument and inserted into the interspinous space. The implant is placed as close to the posterior aspect of the lamina as possible. An adjustment wing is then fastened to the implant and positioned as close to the midline as possible. The incision is then closed, and patients without significant comorbidities are typically allowed to return home on the same day as surgery.

Post-Procedure Therapy

A formal physical therapy program should be implemented post-operatively. Some patients may benefit from several occupational therapy visits. Rehabilitation may take as long as 6 months and include stretching during the first month, floor exercise program, and sports activities in the 5th and 6th months as tolerated. The goals of the therapy program should include instruction in a long-term home-base exercise program (refer to F.12 Therapy-Active).

Return to Work

Barring complications, the patient may be able to return to limited duty after one to two weeks. Sitting upright is limited to 30-45 minutes for the first two weeks. Lifting limits are Zero to 10 pounds for the first 6 weeks post-procedure. If successful, patients may return to medium work category (20-50 pounds per U.S. Department of Labor standards) at 4 to 6 months.

G.10 Laser Discectomy

Involves the delivery of laser energy into the center of the nucleus pulposus using fluoroscopically guided laser fiber under local anesthesia. The energy denatures protein in the nucleus, causing a structural change, which is intended to reduce intradiscal pressure. Its effectiveness has not been shown. Laser discectomy is not recommended.

G.11 Artificial Lumbar Disc Replacement

Description

This involves the insertion of a prosthetic device into an intervertebral space from which a degenerated disc has been removed, sparing only the peripheral annulus. The endplates are positioned under intraoperative fluoroscopic guidance for optimal placement in the sagittal and frontal planes. The prosthetic device is designed to distribute the mechanical load of the vertebrae in a physiologic manner and maintain ROM.

General selection criteria for lumbar disc replacement includes symptomatic one-level degenerative disc disease. The patient must also meet fusion surgery criteria, and if the patient is not a candidate for fusion, a disc replacement procedure should not be considered. Additionally, the patient should be able to comply with pre-and post-surgery protocol.

There is some evidence that disc replacement has a slight advantage over multidisciplinary intensive treatment - 60 hours over 5 weeks. Multi-disciplinary therapy of some type should always be trialed before surgical consideration given the inherent risks of surgery. There is strong evidence that disc replacement is not inferior to fusion at 24 months for relief of back pain, reduction of disability and provision of patient satisfaction. There is good evidence that the Charite disc is not inferior to allograft fusion with the BAK cage for single level disease and some evidence that the ProDisc is non –inferior to circumferential fusion with iliac crest autograft for single level disease.

There is some evidence that a two-level lumbar disc replacement is not inferior to circumferential fusion in patients with 2 level degenerative disc disease 24 months after surgery. However, at this time the FDA has approved this procedure for only one level.

Long-term follow-up studies for several of the current discs is lacking. Patients who had a lumbar ProDisc-L placed had lower scores at 5 years than previously, although 88% were satisfied or somewhat satisfied and 60% would undergo the procedure again. Seventeen-year follow up of Charite disc replacement found spontaneous ankylosis in 60% and reoperation in 11%. There was no adjacent level degeneration in the 17% of functional implants. Patient with ankylosis were more satisfied than those without.

The ten year outcome for the Acro-flex lumbar disc replacement on a small series of patients reported a 39.3% rate of surgical revision most with conversion to fusion. The study also reported adjacent level disc degeneration in the majority of those with disc disease and 50% of

those with fusion. There is good evidence from a comparison of ProDisc-L versus circumferential fusion that arthroplasty is not inferior to fusion and for preservation of motion over fusions. There is some evidence from a five year follow up of ProDisc-L versus circumferential fusion that arthroplasty reduces the risk of adjacent disease. This study found a three times lower rate of new adjacent disc disease for disc replacement (6.7% versus 23.8%). The rate of surgery at an adjacent level did not differ significantly. Both groups improved in most scores similarly.

The theoretical advantage of total disc arthroplasty is that it preserves range of motion and physiologic loading of the disc. This could be an advantage for adults who are physically active. Studies do not demonstrate a long-term advantage of measured function or pain over comparison groups undergoing fusion. The longevity of this prosthetic device has not yet been determined. Significant technical training and experience is required to perform this procedure successfully. Surgeons must be well-versed in anterior spinal techniques and should have attended appropriate training courses, or have undergone training during a fellowship. Mentoring and proctoring of procedures is highly recommended. Reasonable pre-operative evaluation may include an angiogram to identify great vessel location. The angiogram may be either with contrast or with magnetic resonance imaging. An assistant surgeon with anterior access experience is required.

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. The purpose of surgery, is to facilitate active therapy by providing short-term relief through reduction of pain. Since most patients with these conditions will improve significantly over time, without invasive interventions, patients must be able to make well-informed decisions regarding their treatment.

<u>Complications</u>

- Nerve and vascular injury.
- Dural tears.
- Sexual dysfunction (retrograde ejaculation).
- Mal-positioning of the prosthesis.
- Suboptimal positioning of the prosthetic may compromise the long-term clinical result.
- Complex Regional Pain Syndrome (CRPS).
- Complications from abdominal surgery (e.g., hernia or adhesions).
- Re-operation due to complications.

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Surgical Indications

- Symptomatic one-level degenerative disc disease established by objective testing (CT or MRI scan followed by positive provocation discogram);
- Symptoms unrelieved after six months of active non-surgical treatment;
- All pain generators are adequately defined and treated;
- All physical medicine and manual therapy interventions are completed;
- Spine pathology limited to one level; and
- Psychosocial evaluation with confounding issues addressed.

Contraindications

- Significant spinal deformity/scoliosis.
- Symptomatic facet joint arthrosis – If imaging findings and physical exam of pain on extension and lateral bending are present, exploration of facet originated pain should be completed prior to disc replacement.
- Spinal instability at the pathologic or adjacent level requiring fusion.
- Deficient posterior elements.
- Infection.
- Any contraindications to an anterior abdominal approach (including multiple prior abdominal procedures).
- Evidence of nerve root compression, depending on the device used.
- Previous compression or burst fracture.
- Multiple-level degenerative disc disease (DDD).
- Spinal canal stenosis.
- Spondylolysis.
- Spondylolisthesis greater than 3 mm.
- Osteopenia, osteoporosis or any metabolic bone disease.

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- Chronic steroid use or use of other medication known to interfere with bone or soft tissue healing.
- Allergy to device components/materials.
- Depending on the device selected, pregnancy or desire to become pregnant.
- Morbid obesity (e.g., body/mass index [BMI] of greater than 40, over 100 pounds overweight).
- Active malignancy.
- Generalized chronic pain.

Post-Operative Treatment
An individualized rehabilitation program based upon communication between the surgeon and the therapist and using the therapies as outlined in Section F. Therapeutic Procedures Non-Operative. In all cases, communication between the physician and therapist is important to the timing of exercise progressions. Bracing may be appropriate. A formal physical therapy program should be implemented post-operatively. Post-operative active treatment will frequently require a repeat of the therapy sessions previously ordered. The implementation of a gentle aerobic reconditioning program (e.g., walking) and back education within the first post-operative week is appropriate in uncomplicated post-surgical cases. Some patients may benefit from several occupational therapy visits to improve performance of ADLs. Participation in an active therapy program which includes restoration of ROM, core stabilization, strengthening, and endurance is recommended to be initiated at the discretion of the surgeon. Lifting and bending are usually limited for several months at least. Sedentary duty may be able to begin within six weeks in uncomplicated cases. The goals of the therapy program should include instruction in a long-term home based exercise program (refer to F.12. Therapy – Active).

G.12 Kyphoplasty

Description
Kyphoplasty is a surgical procedure for the treatment of symptomatic thoracic or lumbar vertebral compression fractures, most commonly due to osteoporosis or other metabolic bone disease, and occasionally with post-traumatic compression fractures and minor burst fractures that do not significantly compromise the posterior cortex of the vertebral body. Pain relief can be expected in approximately 90% of patients. There is good evidence that kyphoplasty provides rapid improvement in function in the initial months after the fracture as compared to non-operative treatment or analgesics alone. There is no clear long-term advantage. The natural history of recovery from vertebral fractures would indicate that most patients will recover in approximately 12 weeks. There is no evidence that kyphoplasty is superior to vertebroplasty.

Complications
Cement leakage occurs in approximately 10% or less of kyphoplasties and may cause

complications. New vertebral compression fracture may occur following kyphoplasty, but their occurrence does not appear to exceed that of osteoporotic patients who did not receive treatment.

Operative Treatment

Kyphoplasty involves the percutaneous insertion of a trocar and inflatable balloon or expanding polymer into the vertebral body, which re-expands the body, elevating the endplates and reducing the compression deformity. Polymethylmethacrylate (PMMA) bone cement is injected under low pressure into the cavity created by the balloon inflation. In contrast to vertebroplasty, which introduces PMMA cement under high pressure, the space created by balloon inflation allows a higher viscosity PMMA to be injected under lower pressure, which may reduce the risks associated with extravertebral extravasation of the material. There may be an advantage to performing the procedure within one month of the fracture, since the elevation of the endplates may be more readily achieved than when the procedure is delayed.

Surgical Indications

There is no evidence that kyphoplasty improves long-term outcome over conservative care. Kyphoplasty is an accepted treatment during the first 12 weeks, for all the following indications:

- Compression fracture, and
- Vertebral height loss between 15% and 85%, and
- Patients whose pain is severe while using analgesics after the first 4 weeks and who are unable to perform activities of daily living.

Contraindications

- Asymptomatic vertebral body compression fracture
- Patient improvement with medical treatment
- The presence of neurologic compromise related to fracture
- High-velocity fractures with a significant burst component
- Significant posterior vertebral body wall fracture
- Severe vertebral collapse (vertebra plana)
- Infection
- Coagulopathy

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G.13 Vertebroplasty

Description

A minimally invasive surgical procedure for the treatment of painful thoracolumbar vertebral compression fractures secondary to osteoporosis or other metabolic bone disease. Traditionally a low-viscosity acrylic bone cement, polymethylmethacrylate (PMMA), is injected with high pressure into the vertebral body under fluoroscopic guidance. Other types of bone cement such as high-viscosity PMMA, glass polymers, hydroxyapatite, and calcium phosphate have recently been made commercially available. The procedure is usually performed under intravenous sedation or light general anesthesia. A bone biopsy needle or trocar needle (11- to 13-gauge) is placed into the vertebral body and cement is injected very slowly under constant fluoroscopic guidance to minimize cement leakage. The goal of the procedure is to stabilize the spine and to relieve pain.

Evidence on long-term follow up for vertebroplasty is currently lacking. While the available information indicates that the majority of fractures will heal after 8 to 12 weeks of conservative treatment, a modest benefit in pain reduction was seen with vertebroplasty compared to controls at 3 and 12 months in two of the three populations studied, though no benefit was seen over controls in the other trial at either time period. Given the current information, it appears that the majority of the benefit of vertebroplasty over nonoperative treatment is in the early term period. The Klazen randomized trial supported a more rapid improvement in pain and function with vertebroplasty after an average of 5.6 weeks post symptoms.

The procedure is not primarily intended to correct spinal deformity. Vertebral body height correction measurements are inconsistent between studies and, as such, are not comparable. The two long-term studies examining lasting restoration of vertebral body height or kyphotic angle found conflicting results.

While observational and open-label studies have indicated that vertebroplasty is effective for pain relief in up to 90% of patients, the internal validity of these findings is problematic due to widespread lack of blinding. Two double-blind, placebo-controlled trials failed to show a benefit over local anesthetic administered in a “sham procedure” for either pain or quality of life. These studies have been criticized for selection bias due to the inclusion of fractures over 3 months old and the failure of most patients to be willing to enroll in a randomized trial.

There is good evidence that vertebroplasty improves pain scores more rapidly than individualized pharmacological therapy for patients with acute osteoporotic vertebral fractures with effects detectable in the first day and persisting up to one year. There is also good evidence that osteoporotic vertebral fractures improve equally with both vertebroplasty and with well-simulated sham vertebroplasty which includes infiltration of the periosteum with local anesthesia. There is good evidence that vertebroplasty does not differ from sham procedure in patients with MRI evidence of edema or fracture; however many of the patients were more than 6 weeks from the initial symptoms and patients could have had pain for up to 12 months.

When considering vertebroplasty, the judgment of the individual treating clinician is essential in taking into consideration the potential risks of conservative management, including prolonged immobilization, muscle wasting, increased risk of pulmonary infection, and deep venous thrombosis that could lead to pulmonary embolism.

Complications

Because the bone cement is of low viscosity, its injection under pressure frequently results in extravertebral extravasation of the material, with rare serious complications such as pulmonary embolism, radiculopathy, and paraplegia. Procedure-related deaths have been reported. While incidence of serious complications are rare, cement leakage alone occurs in in up to 80% of vertebroplasties, and the long-term implications of clinically silent cement leakages remain poorly understood. Use of high-viscosity PMMA may help minimize extravasation rates, and thus the risk of leakage-related complications.

New vertebral compression fractures may occur following vertebroplasty. One study showed a significant association with an increased incidence in the total number of new vertebral fractures, but when analyzed by the number of patients with new fractures the risk loses statistical significance. Another study saw an increase but was underpowered to report significance. Yet another study found a non-significant reduction. Still other studies reported only clinically significant incident vertebral fractures, and they also found non-significant reductions.

It appears that there may be a risk of new vertebral fractures adjacent to the procedure site when more than one vertebra is treated and also with uncorrected vitamin D deficiency. However, when taken as a whole, occurrence of new vertebral compression fractures following vertebroplasty does not appear to exceed that of osteoporotic patients who did not undergo the procedure.

Indications

The available information suggests that vertebroplasty may be considered for a selected subgroup of patients with painful vertebral compression fractures if they:

- have been radiographically confirmed,
- have been localized clinically to the level of the vertebral fracture,
- are unable to perform activities of daily living,
- have failed to respond to at least 4 weeks of conservative management,
- are between 4 and 12 weeks since pain onset,
- sufficiently healthy to undergo surgery if necessary for decompression,
- have a vertebral height loss between 15% and 85%, and
- intact posterior wall

Contraindications
Any of the following:

- Asymptomatic vertebral body compression fracture;
- Patient improvement with medical treatment;
- The presence of neurologic compromise related to the fracture;
- High velocity fractures with a significant burst component;
- Posterior vertebral body wall fracture;
- Severe vertebral collapse (vertebra plana);
- Spinal canal stenosis;
- Allergy to bone cement or opacification agents;
- Active or incompletely treated infection; or
- Uncorrectable coagulopathy

G.14 Percutaneous Radiofrequency Disc Decompression

Percutaneous Radiofrequency Disc Decompression is an investigational procedure that introduces a 17 gauge cannula under local anesthesia and fluoroscopic guidance into the nucleus pulposus of the contained herniated disc, using radiofrequency energy to dissolve and remove disc material. Pressure inside the disc is lowered as a result. There have been no randomized clinical trials of this procedure at this time. Percutaneous radiofrequency disc decompression is not recommended.

G.15 Nucleus Puposus Replacement

Nucleus Puposus Replacement involves the introduction of a prosthetic implant into the intervertebral disc, replacing the nucleus while preserving the annulus fibrosus. It is limited to investigational use in the United States at this time. It is not recommended.

G.16 Epiduroscopy and Epidural Lysis of Adhesions

Refer to F.4. Injections – Other (Including Radio Frequency).

G.17 Interaoperative Monitoring

Interaoperative Monitoring is a common intraoperative electrodiagnostic technique that may include somatosensory evoked potentials (SSEP), motor evoked potentials (MEP), or pedicle screw monitoring. The monitoring procedure is frequently used to evaluate spinal cord integrity and screw placement during the operative procedure.