

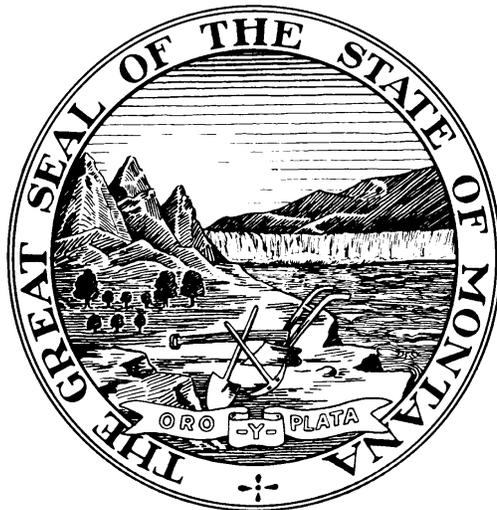
Low Back Pain

Montana Utilization and Treatment Guidelines

Effective July 1, 2011

**Presented by:
State of Montana**

**Department of Labor and Industry
EMPLOYMENT RELATIONS DIVISION**



A. Table of Contents

A. Table of Contents	
B. General Guideline Principles	3
C. Initial Diagnostic Procedures	6
D. Follow-up Diagnostic Imaging and Testing Procedures	10
D1. Imaging Studies	10
D2.a. Electrodiagnostic Testing	12
D2.b. Injections - Diagnostic	14
D2.c. Personality/Psychological/Psychosocial Evaluation	17
D2.d. Provocation Discography	18
D2.e. Thermography	22
D3. Special Tests	22
E. Therapeutic Procedures - Non-operative	25
E1. Acupuncture	25
E2. Biofeedback	27
E3. Injections - Therapeutic	27
E4. Medications	34
E5. Occupational Rehabilitation Programs	38
E6. Orthotics	40
E7. Patient Education	40
E8. Personality/Psychological/Psychosocial Intervention	41
E9. Restriction of Activities	42
E10. Return to Work	42
E11. Therapy - Active	43
E12. Therapy - Passive	46
E13. Vocational Rehabilitation	54
F. Therapeutic Procedures - Operative	55

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 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 Time frames for specific interventions commence once treatments have been initiated, not on the date of injury. Obviously, duration will be impacted by patient compliance, as well as availability of services. Clinical judgment may substantiate the need to accelerate or decelerate the time frames discussed in this document.

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 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.

7. RE-EVALUATE 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 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 time frame, whenever possible. It is important to note that time frames may not be pertinent to injuries that do not involve work-time loss or are not occupationally related.

10. RETURN-TO-WORK is therapeutic, assuming the work is not likely to aggravate the basic problem or increase long-term pain. The practitioner must provide specific physical limitations and the patient should 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 experience in ergonomics, 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 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/accepted*,” 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 or consensus statement attached to it. Those procedures considered inappropriate, unreasonable, or unnecessary are designated in the guideline as being “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.

C. Initial Diagnostic Procedures

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

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

HISTORY-TAKING AND PHYSICAL EXAMINATION (Hx & PE) are generally accepted, well-established and widely used procedures that establish the foundation/basis for and dictates subsequent stages of diagnostic and therapeutic procedures. When findings of clinical evaluations and those of other diagnostic procedures are not complementing each other, the objective clinical findings should have preference. The medical records should reasonably document the following.

C.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. The mechanism of injury should include a detailed description of the incident and the position of the body before, during, and at the end of the incident. Inclusion of normal work body postures, frequency during the workday, and lifting/push/pull requirements should be included in the absence of a known specific incident.
2. Location of pain, nature of symptoms, and alleviating/exacerbating factors (e.g., sitting tolerance). The history should include both the primary and secondary complaints (e.g., primary low back pain, secondary hip, groin). The use of a patient completed pain drawing, Visual Analog Scale (VAS), is highly recommended, especially during the first two weeks following injury to assure that all work related symptoms are addressed;
3. Presence and distribution of lower extremity numbness, paresthesias, or weakness, especially if precipitated by coughing or sneezing;
4. Alteration in bowel, bladder, or sexual function; and for female patients, alteration in their menstrual cycle;
5. 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; and
6. Ability to perform job duties and activities of daily living.

C.1.b Past History

1. Past medical includes neoplasm, gout, arthritis, hypertension, kidney stones, and diabetes;
2. Review of systems includes symptoms of rheumatologic, neurologic, endocrine, neoplastic, infectious, and other systemic diseases;
3. Smoking history;
4. Vocational and recreational pursuits.

C.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, quality of motion, and presence of muscle spasm. Motion evaluation of specific joints may be indicated;
5. Examination of thoracic spine and pelvis;
6. Nerve tension testing;
7. Sensory and motor examination of the lower extremities with specific nerve root focus;
8. Deep tendon reflexes with or without Babinski's;
9. If applicable to injury, anal sphincter tone and/or perianal sensation; and
10. If applicable, abdominal examination, vascular examination, circumferential lower extremity measurements, or evaluation of hip or other lower extremity abnormalities;
11. If applicable, Waddell Signs, which include 5 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 3 out of 5 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. Their presence of 3 out of 5 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 3 out of 5 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. Refer to Section D.2.c. Personality/Psychological/Psychosocial Evaluation.

C.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.

C.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, but no difference in 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. Unexplained or persistent low back pain for at least 6 weeks or pain that is worse with rest;
4. Localized pain, fever, constitutional symptoms, or history or exam suggestive of intravenous drug abuse, prolonged steroid use, or osteomyelitis;
5. Suspected lesion in the lumbosacral spine due to systemic illness such as a rheumatic/rheumatoid disorder or endocrinopathy. Suspected lesions may require special views;
6. Past medical history suggestive of pre-existing spinal disease, osteoporosis, spinal instrumentation, or cancer; and
7. Prior to high-velocity/low amplitude manipulation or Grade IV to V mobilization.

C.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, or underlying rheumatologic disorder, connective tissue disorder, or based on history and/or physical examination. Laboratory tests can provide useful diagnostic information. Tests include, but are not limited to:

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

D. 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. 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 upon availability, a patient's tolerance, and/or the treating practitioner's familiarity with the procedure.

D.1 Imaging Studies

Imaging studies are generally accepted, well-established and widely used diagnostic procedures. In the absence of myelopathy, or progressive neurological changes, or history of cancer, imaging usually is not appropriate until conservative therapy has been tried and failed. Six to eight weeks of treatment are usually 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 upon 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, annular tears, or 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. Therefore, the existence of these anatomic findings should not be considered relevant without physiologic and clinical correlation in an individual patient.

The studies in the sections below are listed in frequency of use, not importance:

D.1.a Magnetic Resonance Imaging (MRI)

Magnetic Resonance Imaging (MRI): 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 implants.

In general, the high field, conventional, MRI provides better resolution. A lower field scan may be indicated when a patient cannot fit into a high field scanner or who 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.

Specialized MRI Scans

MRI with 3-dimensional reconstruction

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.

Dynamic-kinetic MRI of the spine

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.

D.1.b Computed Axial Tomography (CT)

Computed Axial Tomography (CT): provides 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.

D.1.c 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. Myelography is an invasive procedure with complications including nausea, vomiting, headache, convulsion, arachnoiditis, cerebral-spinal fluid (CSF) leakage, allergic reactions, bleeding, and infection. Therefore, myelography should only be considered when CT and MRI are unavailable, for morbidly obese patients or those who have undergone multiple operations, and when other tests prove non-diagnostic in the surgical candidate. The use of small needles and a less toxic, water-soluble, nonionic contrast is recommended.

D.1.d 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 or tumorous conditions.

D.1.e Lineal Tomography

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

D.1.f Bone Scan (Radioisotope Bone Scanning)

Bone Scan (Radioisotope Bone Scanning) is generally accepted, well-established, and widely used. Bone scanning is more sensitive but less specific than MRI. ^{99m}Techetium diphosphonate uptake reflects osteoblastic activity and may be useful in diagnosing metastatic/primary bone tumors, stress fractures, osteomyelitis, and inflammatory lesions, but cannot distinguish between these entities.

D.1.g Other Radioisotope Scanning

Other Radioisotope Scanning: Indium and gallium scans are generally accepted, well-established, and widely used procedures usually to help diagnose lesions seen on other diagnostic imaging studies. ⁶⁷Gallium citrate scans are used to localize tumor, infection, and abscesses. ¹¹¹Indium-labeled leukocyte scanning is utilized for localizing infection or inflammation.

D.1.h 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, since 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.

D.1.i Diagnostic Ultrasound

Diagnostic ultrasound is not recommended for patients with LBP. Ultrasound has not been shown to result in improved patient outcomes or diagnoses other than minor applications. It is not invasive, does not have adverse effects, and is moderately costly. There are other imaging techniques which are currently shown to be useful for diagnosis in patients with LBP. For most imaging purposes, CT and MRI are superior.

D2.a. Electrodiagnostic Testing

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

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.

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.

D.2.a.ii Portable Automated Electrodiagnostic Device

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.

D.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.

D.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.

D.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 9 rows and 7 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.

D.2.a.vi Surface EMG in combination with Range of Motion and/or Functional Capacity Evaluation

This test is 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. The test also purports to determine the significance of disc pathology and the age of an injury. It has not been evaluated in a setting which tests a spectrum of patients commonly seen in clinical practice, using an interpretation which is tested against a diagnostic reference standard. Therefore, it is not suitable as a diagnostic test for low back pain and its use for this purpose is not recommended.

D2.b. Injections - Diagnostic

D.2.b.i-vi Diagnostic Injections

Diagnostic spinal injections are generally accepted, well-established procedures. These injections may be useful for localizing the source of pain, and may have added therapeutic value when combined with injection of therapeutic medication(s). Each diagnostic injection has inherent risks, and risk versus benefit should always be evaluated when considering injection therapy.

Indications - Since these procedures are invasive, less invasive or non-invasive procedures should be considered first. 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) and the source of pain symptoms. Because injections are invasive with an inherent risk, 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 diagnostic blocks listed merely in an attempt to identify 100% of the pain generators.

Interpretation - The interpretation of the test results are primarily based on functional change, symptom report, and pain response (via a recognized pain scale), before and at an appropriate time period after the injection. 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 Section E.3. Injections – Therapeutic for 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 be evident to other reviewers. This entails, at a minimum, documentation of patient response immediately following the procedure with details of any symptoms with a response and the degree of response. Additionally, a log must be recorded as part of the medical record which documents response, if any, on an hourly basis for, at a minimum, 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. Practitioners must carefully weigh the diagnostic value of

the procedure against the possible therapeutic value.

Special Requirements for Diagnostic Injections - Since multi-planar fluoroscopy during procedures is required to document technique and needle placement, an experienced physician should perform the procedure. Permanent images are required to verify needle placement. The subspecialty disciplines of the physicians performing the injections may be varied, including, but not limited to: anesthesiology, radiology, surgery, or physiatry. They must also be knowledgeable in radiation safety.

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. Permanent paresis, anaphylaxis, and arachnoiditis have been rarely reported with the use of epidural steroids.

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) possible pregnancy.

Relative contraindications to diagnostic injections may include: allergy to contrast, poorly controlled Diabetes Mellitus and hypertension. Drugs affecting coagulation require restriction from use. The following are suggested time period restrictions:

- Aspirin-withhold for seven days;
- NSAIDs-withhold for three days;
- Clopidogrel-withhold for 3 days;
- Other anti-platelet therapy and anti-coagulants should also be addressed individually by a knowledgeable specialist.

D.2.b.vii Specific Diagnostic Injections

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

D.2.b.vii.A 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). ISIS suggests controlled blocks – using either placebo or anesthetics with varying lengths of activity (i.e., bupivacaine longer than lidocaine). To be a positive diagnostic block, the patient should report a reduction of pain of 80% or greater relief from baseline for the length of time appropriate for the local anesthetic used. In almost all cases, this will mean a reduction of pain to 1 or 2 on the Visual Analog Scale (VAS) 10-point scale correlated with functional improvement. The patient should also identify activities of daily living (which may include

measurements of range of motion) that are impeded by their pain and can be observed to document 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 the Pain Disability Questionnaire of the American Medical Association (AMA) Guides to the Evaluation of Permanent Impairment (6th Edition).

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.

- Frequency and Maximum Duration: May be repeated once for comparative blocks. Limited to 4 levels

D.2.b.vii.B Transforaminal Injections

Transforaminal injections are generally accepted and useful in identifying spinal pathology. When performed for diagnosis, small amounts of local anesthetic up to a total volume of 1.0 cc should be used to determine the level of nerve root irritation. A positive diagnostic block should result in a positive diagnostic functional benefit and an 80% reduction in nerve-root generated pain appropriate for the anesthetic used as measured by accepted pain scales (such as a VAS).

- Time to produce effect: Less than 30 minutes for local anesthesia; corticosteroids up to 72 hours for most patients
- Frequency and Maximum Duration: Once per suspected level. Limited to two levels

D.2.b.vii.C Zygapophyseal (Facet) Blocks

Facet blocks are generally accepted but should not be considered diagnostic blocks for the purposes of determining the need for a rhizotomy (radiofrequency medial branch neurotomy), nor should they be done with medial branch blocks.

These blocks should not be considered a definitive diagnostic tool. They may be used diagnostically to direct functional rehabilitation programs. A positive diagnostic block should result in a positive diagnostic functional benefit and an 80% reduction in pain appropriate for the anesthetic used as measured by accepted pain scales (such as a VAS). They then may be repeated per the therapeutic guidelines when they are accompanied by a functional rehabilitation program. (Refer to section E. 3. a. Therapeutic Spinal Injections).

- Time to produce effect: Less than 30 minutes for local anesthesia; corticosteroids up to 72 hours for most patients.
- Frequency and maximum Duration: Once per suspected level, limited to two levels.

D.2.b.vii.D Sacroiliac Joint Injection

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.

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. There should be documented relief from previously painful maneuvers (e.g., Patrick's test) and at least 80% pain relief on post-injection physical exam (as measured by accepted pain scales such as a VAS) correlated with functional improvement. Sacroiliac joint blocks should facilitate functionally directed rehabilitation programs.

- Time to produce effect: Up to 30 minutes for local anesthetic
- Frequency and Maximum Duration: 1

D.2.c Personality/Psychological/Psychosocial Evaluation

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

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 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.

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:

1. Employment history;
2. Interpersonal relationships — both social and work;
3. Leisure activities;
4. Current perception of the medical system;
5. Results of current treatment;
6. Perceived locus of control; and
7. 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 (DSM) of Mental Disorders

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 Medical Treatment Guidelines.

- **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.

D2.d. Provocation Discography

D.2.d.i Provocation discography

Description - Discography is an accepted, but rarely indicated, invasive diagnostic procedure to identify or refute a discogenic source of pain for patients who are surgical candidates. 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.

D.2.d.ii Indications for provocation discography

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. A patient who does not desire operative therapeutic intervention is not a candidate for an invasive non-therapeutic intervention, such as provocation discography.

Discography may prove useful for the evaluation of the pre-surgical spine, such as pseudarthrosis, discogenic pain at levels above or below a prior spinal fusion, annular tear, or internal disc disruption.

Discography may show 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 should not be considered for invasive treatment, discography should not be performed on these patients. In symptomatic patients with annular tears on discography, 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.

Discography is not useful in previously operated discs, but may have a limited place in the work-up of pseudarthrosis. Discography may prove useful in evaluating the number of lumbar spine levels that might require fusion. CT-Discography provides further detailed information about morphological abnormalities of the disc and possible lateral disc herniations.

D.2.d.iii Pre-conditions for provocation discography

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

A) 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 noninvasive 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.

B) Psychosocial Evaluation has been completed. There is some evidence that false positives and complaints of long-term pain arising from the procedure itself occur more frequently in patients with somatoform disorders. Therefore, discograms should not be performed on patients with somatoform disorders.

C) Patients who are considered surgical candidates (e.g., symptoms are of sufficient magnitude and the patient has been informed of the possible surgical options that may be available based upon the results of discography). Discography should never be the sole indication for surgery.

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

D.2.d.iv Complications of provocation discography

Complications include, but are not limited to, discitis, nerve damage, chemical meningitis, pain exacerbation, and anaphylaxis therefore, prior to consideration of discography, the patient should undergo other diagnostic modalities in an effort to define the etiology of the patient's complaint including psychological evaluation, myelography, CT and MRI.

D.2.d.v Contraindications for provocation discography

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

D.2.d.vi Special Considerations for provocation discography

A) Discography should not be performed by the physician expected to perform the subsequent surgical procedure. The procedure should be carried out by an experienced individual who has received specialized training in the technique of provocation discography.

B) 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. Abnormal disc levels may be repeated to confirm concordance.

C) Sterile technique must be utilized.

D) Judicious use of light sedation during the procedure is acceptable, represents the most common practice nationally at the current time, and is recommended by most experts in the field. The patient must be awake and able to accurately report pain levels during the provocation portion of the procedure.

E) The discography should be performed using a manometer to record pressure. Pressure should not exceed 50 pounds per square inch (psi) above opening pressure.

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

G) It is recommended that a post-discogram CT be considered as it frequently provides additional useful information about disc morphology or other pathology.

D.2.d.vii 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 and 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. The false positive rate appears to drop to approximately 25% using a pressure of 20 psi above opening pressure in a population with low back pain.

A) 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.

B) Reporting of 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.

1. Unequivocal Discogenic Pain

- stimulation of the target disc reproduces concordant pain
- the pain is registered as at least 7 on a 10-point VAS.
- the pain is reproduced at a pressure of less than 15 psi above opening pressure;
and
- stimulation of two adjacent discs does not produce pain at all

2. Definite Discogenic Pain

- stimulation of the target disc reproduces concordant pain
- the pain is registered as at least 7 on a 10-point VAS.
- the pain is reproduced at a pressure of less than 15 psi above opening pressure;
and
- stimulation of at least one adjacent disc does not produce pain at all

3. Highly Probable Discogenic Pain

- stimulation of the target disc reproduces concordant pain
- that pain is registered as at least 7 on a 10-point VAS.
- that the pain is reproduced at a pressure of less than 50 psi above opening pressure; and
- stimulation of two adjacent discs does not produce pain at all

4. Probable Discogenic Pain

- stimulation of the target disc reproduces concordant pain
- that pain is registered as at least 7 on a 10-point VAS.
- the pain is reproduced at a pressure of less than 50 psi above opening pressure;
and

- stimulation of one adjacent disc does not produce pain at all, and stimulation of another adjacent disc at greater than 50 psi, produces pain, but the pain is not concordant.

Multiple combinations of factors are possible. However, if the patient does not qualify for at least a 'Probable Discogenic Pain' level, 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: Repeat Discography is rarely indicated

D.2.e Thermography

Thermography: is an accepted and established procedure, but has no use as a diagnostic test for low back pain. It may be used to diagnose regional pain disorders and in these cases, refer to the Department's Complex Regional Pain Syndrome/Reflex Sympathetic Dystrophy Medical Treatment Guidelines.

D.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 the following sections are listed in alphabetical order, not by importance.

D.3.a Computer-Enhanced Evaluations

Computer-Enhanced Evaluations may include isotonic, isometric, isokinetic and/or isoinertial measurement of movement, range of motion, endurance, or strength. Values obtained can include degrees of motion, torque forces, pressures, 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. Can monitor improvements in strength every 3 to 4 weeks up to a total of 6 evaluations.

D.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, coordination and strength, worker habits, employability as well as psychosocial, cognitive, and sensory perceptual aspects of competitive employment may be evaluated. 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.

When an FCE is being used to determine return to a specific jobsite, the provider is responsible for fully understanding the job duties. A jobsite evaluation is frequently necessary. FCEs cannot be used in isolation to determine work restrictions. The authorized treating physician must interpret the FCE in light of the individual patient's presentation and medical and personal perceptions. FCEs should not be used as the sole criteria to diagnose malingerer.

Full FCEs are rarely necessary. In many cases, a work tolerance screening will identify the ability to perform the necessary job tasks.

- Frequency: Can be used initially to determine baseline status. Additional evaluations can be performed to monitor and assess progress and aid in determining the endpoint for treatment.

D.3.c Job site Evaluation

Job site 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) range of motion; (d) torque/force; (e) lifting/carrying; (f) cognitive demands; (g) social interactions; (h) visual perceptual; (i) sensation; (j) coordination; (k) environmental requirements (l) repetitiveness; and (m) essential job functions. Job descriptions provided by the employer are helpful but should not be used as a substitute for direct observation by a qualified individual (e.g., physical therapist, occupational therapist, vocational rehabilitation counselor, nurse case manager, etc.).

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:

1. To determine if there are potential contributing factors to the person's condition and/or for the physician to assess causality;
2. To make recommendations for, and to assess the potential for ergonomic changes;
3. To provide a detailed description of the physical and cognitive job requirements;
4. 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;
5. To give detailed work/activity restrictions.
 - Frequency: One time with additional visits as needed for follow-up per jobsite.

D.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 rehabilitation assistance 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.

D.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 may be used when a full Functional Capacity Evaluation is not indicated. It may include a test or procedure to specifically identify and quantify work-relevant cardiovascular, 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.

E. Therapeutic Procedures - Non-operative

Before initiation of any therapeutic procedure, the authorized treating provider and insurer must consider these 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 “Return-to-Work” in this section 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 education to the patient. No treatment plan is complete without addressing issues of individual and/or group patient education as a means of facilitating self-management of symptoms.

Lastly, 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.

Non-operative treatment procedures for low back pain can be divided into two groups: conservative care and rehabilitation. Conservative care is treatment applied to a problem in which spontaneous improvement is expected in 90% of the cases within three months. It is usually provided during the tissue-healing phase and lasts no more than six months, and often considerably less. Rehabilitation is treatment applied to a more chronic and complex problem in a patient with de-conditioning and disability. It is provided during the period after tissue healing to obtain maximal medical recovery. Treatment modalities may be utilized sequentially or concomitantly depending on chronicity and complexity of the problem, and treatment plans should always be based on a diagnosis utilizing appropriate diagnostic procedures.

E.1 Acupuncture

Acupuncture is an accepted and widely used procedure for the relief of pain and inflammation, and there is some scientific evidence to support its use. 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. While it is commonly used when pain medication is reduced or not tolerated, it may be used as an adjunct to physical rehabilitation and/or surgical intervention to hasten the return of functional activity. Acupuncture should be performed by licensed practitioners.

E.1.a Acupuncture without Electrical Stimulation

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

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

E.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.

E.1.c Time Frames For Acupuncture with/without Electrical Stimulation

Total Time Frames For Acupuncture and Acupuncture with Electrical Stimulation: Time frames are not meant to be applied to each of the different types of acupuncture separately. The time frames are to be applied to all acupuncture treatments regardless of the type or combination of therapies being provided.

1. Time to produce effect: 3 to 6 treatments
2. Frequency: 1 to 3 times per week
3. Optimum duration: 1 to 2 months
4. Maximum duration: 14 treatments

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

E.1.d 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 Active Therapy (Therapeutic Exercise) and Passive Therapy sections (Massage and Superficial Heat and Cold Therapy) for a description of these adjunctive acupuncture modalities and time frames.

E.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. Electronic instrumentation is used to monitor the targeted physiology and then displayed or fed back to the patient visually, auditorially, or tactilely, with coaching by a biofeedback specialist. Biofeedback is provided by clinicians certified in biofeedback and/or who have documented specialized education, advanced training, or direct or supervised experience qualifying them to provide the specialized treatment needed (e.g., surface EMG, EEG, or other).

Treatment is individualized to the patient's work-related diagnosis and needs. Home practice of skills is required for mastery and may be facilitated by the use of home training tapes. The ultimate goal of biofeedback treatment is to normalize 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 must be motivated to learn and practice biofeedback and self-regulation techniques.

Indications for biofeedback include individuals who are suffering from 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 emotional stress/pain responses such as anxiety, depression, anger, sleep disturbance, and other central and autonomic nervous system imbalances. Biofeedback is often used in conjunction with other treatment modalities.

- Time to produce effect: 3 to 4 sessions
- Frequency: 1 to 2 times per week
- Optimum duration: 5 to 6 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.

E3. Injections - Therapeutic

E.3.a Therapeutic Spinal Injections

Description - Therapeutic spinal injections may be used after initial conservative treatments, such as physical and occupational therapy, medication, manual therapy, exercise, acupuncture,

etc., have been undertaken. Therapeutic injections should be used only after imaging studies and diagnostic injections have established pathology. Injections are invasive procedures that can cause serious complications; thus clinical indications and contraindications should be closely adhered to. The purpose of spinal injections is to facilitate active therapy by providing short-term relief through reduction of pain and inflammation. All patients should continue appropriate exercise with functionally directed rehabilitation. Active treatment, which patients should have had prior to injections, will frequently require a repeat of the sessions previously ordered (Refer to section E. 11, Active Therapy). Injections, by themselves, are not likely to provide long-term relief. Rather, active rehabilitation with modified work achieves long-term relief by increasing active ROM, strength, and stability. If the first injection does not provide a diagnostic response with temporary and sustained pain relief substantiated by accepted pain scales, (i.e., 80% pain reduction on visual analog scale), and improvement in function, similar injections should not be repeated.

Special Considerations - For all injections (excluding trigger point), multi-planar fluoroscopic guidance during procedures is required to document technique and needle placement, and should be performed by a physician experienced in the procedure. Permanent images are required to verify needle replacement. The subspecialty disciplines of the physicians performing 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) and/or completed fellowship training in pain medicine with interventional training. They must also be knowledgeable in radiation safety.

Complications - General complications of spinal injections may include transient neurapraxia, local pain, nerve injury, infection, headache, urinary retention, and vasovagal effects. Epidural hematoma, permanent neurologic damage, dural perforation and CSF leakage; and/or spinal meningeal abscess may also occur. Permanent paresis, anaphylaxis, and arachnoiditis 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.

Contraindications - Absolute contraindications to therapeutic injections include: (a) bacterial infection—systemic or localized to region of injection, (b) bleeding diatheses, (c) hematological conditions, and (d) possible pregnancy.

Relative contraindications to diagnostic injections may include: allergy to contrast, poorly controlled Diabetes Mellitus, and hypertension. Drugs affecting coagulation require restriction from use. The following are suggested time period restrictions:

- Aspirin-withhold for seven days
- NSAIDs-withhold for three days
- Clopidogrel-withhold for 3 days
- Other anti-platelet therapy and anti-coagulants should also be addressed individually by a knowledgeable specialist

E.3.a.i Epidural Steroid Injection (ESI)

Description - Epidural steroid injections are injections of corticosteroid into the epidural space. The purpose of ESI is 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. ESI uses three approaches: transforaminal, interlaminar (midline), and caudal. The transforaminal approach is the preferred method for unilateral, single-level pathology and for post-surgical patients. There is good evidence that the transforaminal approach can deliver medication to the target tissue with few complications and can be used to identify the specific site of pathology. The interlaminar approach is the preferred approach for multi-level pathology or spinal stenosis. Caudal therapeutic injections may be used, but it is difficult to target the exact treatment area, due to diffuse distribution.

Needle Placement - Multi-planar fluoroscopic imaging is required for all epidural steroid injections. Contrast epidurograms allow one to verify the flow of medication into the epidural space. Permanent images are required to verify needle replacement.

Indications - There is some evidence that epidural steroid injections are effective for patients with radicular pain or radiculopathy (sensory or motor loss in a specific dermatome or myotome). Up to 80% of patients with radicular pain may have initial relief. However, only 25-57% are likely to have excellent long-term relief. Although there is no evidence regarding the effectiveness of ESI for non-radicular disc herniation, it is an accepted intervention. Only patients who have 1) pain affected by activity and 2) annular tears verified by appropriate imaging may have injections for axial pain.

There is some evidence that ESI injections are not effective for spinal stenosis without radicular findings. Additionally, there is some evidence that patients who smoke or who have pain unaffected by rest or activity are less likely to have a successful outcome from ESIs.

- Time to produce effect: Local anesthetic, less than 30 minutes; corticosteroid, 48 to 72 hours for 80% of patients and 72 hours to 2 weeks for 20% of patients.
- 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. 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 (lasting between 2 and 6 weeks) substantiated by accepted pain scales, (i.e., 80% pain reduction as measured by tools such as visual analog scale (VAS), and improvement in function, similar injections should not be repeated.
- Optimum duration: Usually 1 to 3 injection(s) over a period of six months depending upon each patient's response and functional gain.
- Maximum duration: Two sessions (consisting of up to three injections each) may be done in one year, as per the patient's response to pain and function. Patients should be

reassessed after each injection for an 80% improvement in pain (as measured by accepted pain scales) and evidence of functional improvement.

E.3.a.ii Zygapophyseal (Facet) Injection

Description - A generally accepted intra-articular or pericapsular injection of local anesthetic and corticosteroid. Medial branch nerve blocks are diagnostic only. There is conflicting evidence to support a long-term therapeutic effect using facet injections. There is no justification for a combined facet and medial branch block.

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; OR patients who have facet findings with a thoracic component. 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.

- Facet injections may be repeated if they result in increased documented functional benefit for at least 4 to 6 weeks and at least an 80% initial improvement in pain scales as measured by accepted pain scales (such as VAS).
- 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. If the first injection does not provide a diagnostic response of temporary and sustained pain relief substantiated by accepted pain scales, (i.e., 80% pain reduction substantiated by tools such as VAS), and improvement in function, similar injections should not be repeated. At least 4 to 6 weeks of functional benefit should be obtained with each therapeutic injection.
- Optimum duration: 2 to 3 injections for each applicable joint per year. Not to exceed two joint levels.
- Maximum Duration: 4 per level per year. Prior authorization must be obtained for injections beyond two levels.

E.3.a.iii Sacroiliac Joint Injection

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

Indications - Primarily diagnostic to rule out sacroiliac joint dysfunction vs. other pain generators. Intra-articular injection can be of value in diagnosing the pain generator. There should be documented relief from previously painful maneuvers (e.g., Patrick's test) on post-

injection physical exam. These injections may be repeated if they result in increased documented functional benefit for at least 6 weeks and at least an 80% initial improvement in pain scales as measured by accepted pain scales (such as VAS). Sacroiliac joint blocks should facilitate a functionally directed rehabilitation program.

- 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. If the first injection does not provide a diagnostic response of temporary and sustained pain relief substantiated by accepted pain scales, (i.e., 80% pain reduction substantiated by tools such as VAS), and improvement in function, similar injections should not be repeated. At least 6 weeks of functional benefit should be obtained with each therapeutic injection.
- Maximum duration: 4 injections per year.

E.3.a.iv Intradiscal Steroid Therapy

Intradiscal Steroid Therapy consists of injection of a steroid preparation into the intervertebral disc under fluoroscopic guidance at the time of discography. There is good evidence that it is not effective in the treatment of suspected discogenic back pain and its use is not recommended.

E.3.b Radio Frequency 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. There is good evidence to support Radio Frequency Medial Branch Neurotomy in the cervical spine but benefits beyond one year are not yet established. Evidence in the lumbar spine is conflicting; however, the procedure is generally accepted. In one study, 60% of patients maintained at least 90% pain relief at 12 months. Radio-frequency Medial Branch Neurotomy is the procedure of choice over alcohol, phenol, or cryoablation. Precise positioning of the probe using fluoroscopic guidance is required since the maximum effective diameter of the device is a 5x8 millimeter oval. Permanent images should be recorded to verify placement of the device.

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: Pain of well-documented facet origin, unresponsive to active and/or passive therapy, unresponsive to manual therapy, and in which a psychosocial screening has been performed (e.g., pain diagram, Waddell's signs, thorough psychosocial history, screening questionnaire). It is generally recommended that this procedure not be performed until three months of active therapy and manual therapy have been completed. 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 section E. 11, Active

Therapy.)

All patients should have a successful response to a diagnostic medial nerve branch block and a separate comparative block. ISIS suggests controlled blocks using either placebo or anesthetics with varying lengths of activity (i.e., bupivacaine longer than lidocaine). To be a positive diagnostic block the patient should report a reduction of pain of 80% or greater from baseline for the length of time appropriate for the local anesthetic used. In almost all cases this will mean a reduction of pain to 1 or 2 on the VAS 10-point scale correlated with functional improvement. The patient should also identify activities of daily living (which may include measurements of range of motion) that are impeded by their pain and can be observed to document 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. A comparative block uses anesthetics with varying lengths of activity.

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.

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.

Requirements for Repeat Radiofrequency Medial Branch Neurotomy (or additional-level RF Neurotomies): In some cases pain may recur. Successful RF Neurotomy usually provides from six to eighteen months of relief.

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.

E.3.c Sacro-iliac (SI) Joint Radiofrequency Denervation

Sacro-iliac (SI) Joint Radiofrequency Denervation is a denervation of the SI joint. This procedure is not recommended as there is no evidence to support its use.

E.3.d Trigger Point Injections and Dry Needling Treatment

Description - Trigger point injections are a generally accepted treatment. Trigger point treatment can consist of dry needling or injection of local anesthetic, with or without corticosteroid, into highly localized, extremely sensitive bands of skeletal muscle fibers that produce local and referred pain when activated. Medication is injected in a four-quadrant manner

in the area of maximum tenderness. Injection 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.

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 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 functional restoration 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 time frame. 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 developing. 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.

E.3.e Prolotherapy

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 are conflicting studies concerning the effectiveness of Prolotherapy in the low back. Lasting functional improvement has not been shown. The injections are invasive, may be painful to the patient, and are not generally accepted or widely used. Therefore, the use of Prolotherapy for low back pain is not recommended.

E.3.f Epiduroscopy and Epidural Lysis of Adhesions

Epiduroscopy and Epidural Lysis of Adhesions is an 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, epidural injection, or mechanical lysis, is not recommended.

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

E.4 Medications

Medication 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. All drugs should be used according to patient needs. A thorough medication history, including use of alternative and over the counter medications, should be performed at the time of the initial visit and updated periodically. Treatment for pain control is initially accomplished with acetaminophen and/or NSAIDs. The patient should be educated regarding the interaction with prescription and over-the-counter medications as well as the contents of over-the-counter herbal products.

The following are medications listed in alphabetical order:

E.4.a Acetaminophen

Acetaminophen is an effective analgesic with antipyretic but not anti-inflammatory activity. Acetaminophen is generally well tolerated, causes little or no gastrointestinal irritation, and is not associated with ulcer formation. Acetaminophen has been associated with liver toxicity in overdose situations or in chronic alcohol use. Patients may not realize that many over-the-counter preparations may contain acetaminophen. The total daily dose of acetaminophen is recommended not to exceed 4 grams per 24-hour period, from all sources, including narcotic-acetaminophen combination preparations.

- Optimum duration: 7 to 10 days.
- Maximum duration: Chronic 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.

E.4.b Muscle Relaxants

Muscle Relaxants are appropriate for muscle spasm with pain. There is strong evidence that 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 side effects of drowsiness or dizziness and the fact that benzodiazepines may be habit-forming.

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

E.4.c Narcotics

Narcotics should be primarily reserved for the treatment of severe low back pain. In mild to moderate cases of low back pain, narcotic 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.

Narcotic 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 narcotic 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 two weeks is acceptable in appropriate cases. Refer to Chronic Pain Guidelines which gives a detailed discussion regarding medication use in chronic pain management.

E.4.d Nonsteroidal Anti-Inflammatory Drugs (NSAIDs)

Nonsteroidal Anti-Inflammatory Drugs (NSAIDs) are useful for pain and inflammation. In mild cases, they may be the only drugs required for analgesia. There are several classes of NSAIDs,

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 US Food and Drug Administration advise that many NSAIDs may cause an increased risk of serious cardiovascular thrombotic events, myocardial infarction, and stroke, which can be fatal. Naproxen sodium does not appear to be associated with increased risk of vascular events. 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 but 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. Certain NSAIDs may have interactions with various other medications. Individuals may have adverse events not listed above. Intervals for metabolic screening are dependent upon the patient's age, 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 Nonsteroidal 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 gastrointestinal 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.

- Optimal 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 are more recent NSAIDs and differ in adverse side effect profiles from the traditional NSAIDs. The major advantages of selective COX-2 inhibitors over traditional NSAIDs are that they have less gastrointestinal 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.

- Optimal 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.

E.4.e Oral Steroids

Oral Steroids have limited use but are accepted in cases requiring potent anti-inflammatory drug effect. There is no evidence supporting oral steroids for patients with low back pain with or without radiculopathy and are not recommended.

E.4.f Intravenous Steroids

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

E.4.g Psychotropic/Anti-anxiety/Hypnotic Agents

Psychotropic/Anti-anxiety/Hypnotic Agents may be useful for treatment of mild and chronic pain, dysesthesias, sleep disorders, and depression. Antidepressant medications, such as tricyclics and Selective Serotonin Reuptake Inhibitors (SSRIs), are useful for affective disorder and chronic pain management. Tricyclic antidepressant agents, in low dose, are useful for chronic pain but have more frequent side effects.

Anti-anxiety medications should generally be limited to short-term use. Combinations of the above agents may be useful.

As a general rule, physicians should access 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 routinely recommended. Refer to the Chronic Pain 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.

E.4.h Tramadol

Tramadol is useful in relief of low back pain and has been shown to provide pain relief equivalent to that of commonly prescribed NSAIDs. Although Tramadol may cause impaired alertness, it is generally well tolerated, does not cause gastrointestinal ulceration, or 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, and tricyclic antidepressants. This medication has physically addictive properties and withdrawal may follow abrupt discontinuation and is not 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.

E5. Occupational Rehabilitation Programs

E.5.a Non-Interdisciplinary Programs

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

Work Conditioning

These programs are usually initiated once reconditioning has been completed but may be offered at any time throughout the recovery phase. Work conditioning 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.

Work Simulation

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

- 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 six weeks must be documented with respect to need and the ability to facilitate positive symptomatic or functional gains.

E.5.b Interdisciplinary Programs

Interdisciplinary programs are well-established treatment for patients with sub-acute and functionally impairing low back pain. They are characterized by a variety of disciplines that participate in the assessment, planning, and/or implementation of an injured worker's program with the goal for patients to gain full or optimal function and return to work. There should be close interaction and integration among the disciplines to ensure that all members of the team interact to achieve team goals. Programs should include cognitive-behavioral therapy as there is good evidence for its effectiveness in patients with chronic low back pain. These programs are for patients with greater levels of disability, dysfunction, de-conditioning and psychological involvement. For patients with chronic pain, refer to the Department's Chronic Pain Disorder Medical Treatment Guidelines.

E.5.b.i Work Hardening

Work Hardening is an 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 workday. This is accomplished by addressing the medical, psychological, behavioral, physical, functional, and vocational components of employability and return-to-work.

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 with documented training in occupational rehabilitation; team physicians having experience in occupational rehabilitation; occupational therapist; physical therapist; case manager; and psychologist. As appropriate, the team may also include: chiropractor, RN, vocational specialist or Certified Biofeedback Therapist.

- Length of visit: Up to 8 hours/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.

E.5.b.ii Spinal Cord Programs

Spinal Cord Systems of Care provide coordinated, case-managed, and integrated service 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 and 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, occupational therapy, physical therapy, psychologist, rehabilitation RN and MD, and therapeutic recreation specialist. As appropriate, the team may also include: rehabilitation counselor, respiratory therapist, social worker, or speech-language pathologist.

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

E6. Orthotics

E.6.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.

E.6.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.

E.6.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 which is prescribed. Harmful effects include de-conditioning of the trunk musculature, skin irritation, and general discomfort.

E.6.d Lumbosacral Bracing

Rigid bracing devices are well accepted and commonly used for post-fusion, scoliosis, and vertebral fractures.

E.7 Patient Education

No treatment plan is complete without addressing issues of individual and/or group patient education as a means of prolonging the beneficial effects of treatment, as well as facilitating self-management of symptoms and injury prevention. The patient should be encouraged to take an active role in the establishment of functional outcome goals. They should be educated on their

specific injury, assessment findings, and plan of treatment. Instruction on proper body mechanics and posture, positions to avoid, self-care for exacerbation of symptoms, and home exercise should also be addressed.

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

E.7.a Back School

Back schools are recommended for treatment of select patients with chronic but not acute or sub-acute LBP. Back schools have been used for almost 40 years for the rehabilitation of LBP patients. The more successful programs appear to have greater reliance on aerobic and endurance exercises and cognitive-behavioral principles than on education or flexibility exercises. There is moderate evidence suggesting that back schools have better short-term effects than other treatments for chronic LBP and that such schools are more effective in an occupational setting than in a non-occupational setting. Back schools are not invasive, have low risk of adverse effects, but are expensive and consequently should be used in select patients who are likely to both achieve benefits and adhere to the program components after discharge.

E.8 Personality/Psychological/Psychosocial Intervention

Psychosocial treatment is generally accepted, widely used, and well-established intervention. This group of therapeutic and diagnostic modalities includes, but is not limited to, individual counseling, group therapy, stress management, psychosocial crises intervention, hypnosis, and meditation. Any evaluation or diagnostic workup should clarify and distinguish between pre-existing psychological conditions versus aggravated psychological conditions versus psychological conditions caused by occupational injury or disease. Psychosocial intervention is recommended as an important component in the total management program that should be implemented as soon as the problem is identified. There is some evidence that early cognitive-behavioral treatment reduces health care use in comparison to written information alone. This can be used alone, or in conjunction with other treatment modalities. Providers treating patients with chronic pain should refer to the Department's Chronic Pain Disorder Medical Treatment Guidelines.

- Time to produce effect: 2 to 4 weeks.
- Frequency: 1 to 3 times weekly for the first 4 weeks (excluding hospitalization, if required), decreasing to 1 to 2 times per week for the second month. Thereafter, 2 to 4 times monthly.
- Optimum duration: 6 weeks to 3 months
- Maximum Duration: 3 to 12 months. Counseling is not intended to delay but to enhance functional recovery. For select patients, longer supervised treatment may be required. If further counseling beyond 3 months is indicated, the authorized treating provider must document every 4 to 6 weeks during treatment what treatment is for pre-existing

psychological conditions versus aggravated psychological conditions versus psychological conditions caused by occupational injury or disease, as well as project a realistic functional prognosis.

E.9 Restriction of Activities

Continuation of normal daily activities is the recommendation for acute and chronic low back pain without neurologic symptoms. There is good evidence against the use of bed rest in cases without neurologic symptoms. Bed rest may lead to de-conditioning and impair rehabilitation. Complete work cessation should be avoided, if possible, since it often further aggravates the pain presentation. Modified return-to-work is almost always more efficacious and rarely contraindicated in the vast majority of injured workers with low back pain.

E.10 Return to Work

Early return-to-work should be a prime goal in treating occupational injuries given the poor return-to-work prognosis for an injured worker who has been out of work for more than six months. It is imperative that the patient be educated regarding the benefits of return-to-work, work restrictions, and follow-up if problems arise. When attempting to return a patient to work after a specific injury, clear objective restrictions of activity level should be made. An accurate job description with detailed physical duty restrictions is often necessary to assist the physician in making return-to-work recommendations. This may require a jobsite evaluation.

Employers should be prepared to offer transitional work. This may consist of temporary work in a less demanding position, return to the regular job with restrictions, or gradual return to the regular job. Company policies which encourage return-to-work with positive communication are most likely to have decreased worker disability.

Return-to-work is defined as any work or duty that the patient is able to perform safely. It may not be the patient's regular work. Due to the large spectrum of injuries of varying severity and varying physical demands in the work place, it is not possible to make specific return-to-work guidelines for each injury. Therefore, the Department recommends the following

E.10.a Establishment of a Return-To-Work Status

Ascertaining a return-to-work status is part of medical care, should be included in the treatment and rehabilitation plan, and addressed at every visit. A description of daily activity limitations is part of any treatment plan and should be the basis for restriction of work activities. In most non-surgical cases, the patient should be able to return-to-work in some capacity or in an alternate position consistent with medical treatment within several days unless there are extenuating circumstances. Injuries requiring more than two weeks off work should be thoroughly documented.

E.10.b Establishment of Activity Level Restrictions

Communication is essential between the patient, employer, and provider to determine appropriate restrictions and return-to-work dates. It is the responsibility of the physician to

provide clear concise restrictions, and it is the employer's responsibility to determine if temporary duties can be provided within the restrictions. For low back pain injuries, the following should be addressed when describing the patient's activity level:

- Lifting limits with the maximum amount of weight to be lifted. This may vary depending on the frequency of the lifting and/or the object height level. Pushing, pulling, as well as bending and twisting at the waist should be considered as well.
- Lower body postures such as squatting, kneeling, crawling, stooping, or climbing should include duration and frequency.
- Ambulatory level for distance, frequency, and terrain should be specified.
- Duration and frequency of sitting, standing, and walking should be delineated. Balance issues should also be considered in these determinations.
- Use of adaptive devices or equipment for proper office ergonomics to enhance capacities can be included.

E.10.c Compliance with Activity Restrictions

In some cases, compliance with restriction of activity levels may require a complete jobsite evaluation, a functional capacity evaluation (FCE) or other special testing. Refer to the "Special Tests" section of this guideline.

E11. Therapy - Active

The following active therapies are widely used and accepted methods of care for a variety of work-related injuries. They are based on the philosophy that therapeutic exercise and/or activity are beneficial for restoring flexibility, strength, endurance, function, range of motion, and can alleviate discomfort. Active therapy requires 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). 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.

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 active therapies described are listed in alphabetical order.

E.11.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

E.11.b Aquatic Therapy

Aquatic Therapy is a well-accepted treatment which consists of the therapeutic use of aquatic immersion for therapeutic exercise to promote strengthening, core stabilization, endurance, range of motion, 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

A self-directed program is recommended after the supervised aquatics program has been established, or, alternatively a transition to a self-directed dry environment exercise program.

E.11.c Functional Activities

Functional Activities are well-established interventions which 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

E.11.d Functional Electrical Stimulation

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

E.11.e Neuromuscular Re-education

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

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

- Maximum duration: 8 weeks

E.11. f Spinal Stabilization

Spinal Stabilization is a generally well-accepted treatment. The goal of this therapeutic program is to strengthen the spine in its neural and anatomic position. The stabilization is dynamic which allows whole body movements while maintaining a stabilized spine. It is the ability to move and function normally through postures and activities without creating undue vertebral stress.

- 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

E.11.g Therapeutic Exercise

Therapeutic Exercise is a generally well-accepted treatment. Therapeutic exercise, with or without mechanical assistance or resistance, may include 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, increased range of motion. Therapeutic exercises are used to promote normal movement patterns, and can also include complementary/alternative exercise movement therapy (with oversight of a physician or appropriate healthcare professional).

There is some evidence to support the effectiveness of yoga therapy in alleviating symptoms and decreasing medication use in uncomplicated low back pain.

- Time to produce effect: 2 to 6 treatments
- Frequency: 3 to 5 times per week
- Optimum duration: 4 to 8 weeks
- Maximum duration: 8 weeks

E.12 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 Section B. 4. General Guideline Principles, Active Interventions. 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.

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

The passive therapies described are listed in alphabetical order.

E.12.a Electrical Stimulation (Unattended)

Electrical Stimulation (Unattended) is an accepted treatment. Once applied, unattended electrical stimulation requires minimal on-site supervision by the physical therapist, occupational therapist, or other provider. Indications include pain, inflammation, muscle spasm, atrophy, decreased circulation, 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

E.12.b Iontophoresis

Iontophoresis is an accepted treatment which consists of the transfer of medication, including, but not limited to, steroidal anti-inflammatories and anesthetics, through the use of electrical stimulation. Indications include pain (Lidocaine), inflammation (hydrocortisone, salicylate), edema (mecholyl, hyaluronidase, salicylate), ischemia (magnesium, mecholyl, iodine), muscle spasm (magnesium, calcium), calcific deposits (acetate), scars, and keloids (sodium chloride, iodine, acetate). There is no proven benefit for this therapy in the low back.

- Time to produce effect: 1 to 4 treatments
- Frequency: 3 times per week with at least 48 hours between treatments
- Optimum duration: 4 to 6 weeks

- Maximum duration: 6 weeks

E.12.c Manipulation

Manipulation is generally accepted, well-established and widely used therapeutic intervention for low back pain. 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.

High velocity, low amplitude (HVLA) technique, chiropractic manipulation, osteopathic manipulation, muscle energy techniques, counter strain, and non-force techniques are all types of manipulative treatment. This 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 physicians. Under these different types of manipulation exist many subsets of different 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 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. Pre-treatment assessment should be performed as part of each manipulative treatment visit to ensure that the correct diagnosis and correct treatment is employed.

High velocity, low amplitude (HVLA) manipulation is performed by taking a joint to its end range of motion and moving the articulation into the zone of accessory joint movement, well within the limits of anatomical integrity. There is good scientific evidence to suggest that HVLA manipulation can be helpful for patients with acute low back pain problems without radiculopathy when used within the first 4 to 6 weeks of symptoms. Although the evidence for sub-acute and chronic low back pain and low back pain with radiculopathy is less convincing, it is a generally accepted and well-established intervention for these conditions. Indications for manipulation include joint pain, decreased joint motion, and joint adhesions. 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: 1 to 6 treatments.
- Frequency: Up to 3 times per week for the first 4 weeks as indicated by the severity of involvement and the desired effect, then up to 2 treatments per week for the next 4 weeks. For further treatments, twice per week or less to maintain function.
- Optimum duration: 8 to 12 weeks
- Maximum duration: 3 months. 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 comorbidities. Refer to the Chronic Pain Guidelines for care beyond 3 months.

E.12.d 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.

E.12.e 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.

E.12.f 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 practitioner's hands. Indications include edema (peripheral or hard and non-pliable edema), muscle spasm, adhesions, the need to improve peripheral circulation and range of motion, or to increase muscle relaxation and flexibility prior to exercise.

In sub-acute low back pain populations there is good evidence that massage can increase function when combined with exercise and patient education. Some studies have demonstrated a decrease in provider visits and pain medication use with combined therapy. One study indicated improved results with acupressure massage. It is recommended that all massage be performed by trained, experienced therapists and be 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

E.12.g Mobilization (Joint)

Mobilization (Joint) is a generally well-accepted treatment. Mobilization is 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 further discussion on Level V joint mobilization please see section on HVLA manipulation [Refer to section 12. d.]. It may include skilled manual joint tissue stretching. Indications include the need to improve joint play, segmental alignment, improve intracapsular arthrokinematics, or reduce pain associated with tissue impingement. Mobilization should be accompanied by active therapy. For Level 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

E.12.h Mobilization (Soft Tissue)

Mobilization (Soft Tissue) is a generally 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. 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

E.12.i Reflexology

Reflexology is a treatment that focuses on massage of reflex points which are believed to be linked to physiological responses and healing of other tissues including those in the back. Reflexology has not been shown to be efficacious for the treatment of chronic LBP and is not recommended.

E.12.j Neuroreflexotherapy

Neuroreflexotherapy is recommended for the treatment of moderate to severe chronic LBP in patients who have failed management with NSAIDs, progressive aerobic exercise program or other exercises, or manipulation.

E.12.k Short-Wave Diathermy

Short-Wave Diathermy is an accepted treatment which 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.

- 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

E.12.l 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, edema and hemorrhage, need to increase pain threshold, reduce muscle spasm, and 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

E.12.m 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.

- Time to produce effect: 1 to 3 sessions
- Frequency: 2 to 3 times per week

- Optimum duration: 30 days
- Maximum duration: 1 month

E.12.n Traction - Mechanical

Traction—Mechanical There is no evidence that mechanical traction is useful for low back pain patients without radicular symptoms. Therefore, it is not recommended in this population. It may be trialed in patients with radicular findings, and if successful, should be shifted to home traction. Traction modalities are contraindicated in patients with tumor, infections, fracture, or fracture dislocation. Non-oscillating inversion traction methods are contraindicated in patients with glaucoma or hypertension. A home lumbar traction unit can be purchased if therapy proves effective.

- Time to produce effect: 1 to 3 sessions up to 30 minutes. If response is negative after 3 treatments, discontinue this modality.
- Frequency: 2 to 3 times per week. A home lumbar traction unit can be purchased if therapy proves effective.
- Optimum duration: 4 weeks
- Maximum duration: 4 weeks

E.12.o Transcutaneous Electrical Nerve Stimulation (TENS)

Transcutaneous Electrical Nerve Stimulation (TENS) is a generally accepted treatment. TENS should include at least one instructional session for proper application and 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

E.12.o.i Interferential Therapy

Interferential therapy is not recommended for treatment of subacute or chronic LBP or radicular pain syndromes. Interferential therapy (IFT) is a form of electrical stimulation using amplitude modulation of two out-of-phase medium-frequency currents to produce a low-frequency current. This procedure is similar to TENS and differs by having less impedance in the tissues and is reportedly more comfortable than traditional TENS treatment. IFT is commonly used in the U.K.

There is no quality evidence demonstrating that interferential therapy produces any benefits in comparison with no treatment among acute LBP patients. There also is no quality evidence that interferential therapy produces any incremental benefits when added to a treatment regimen. Interferential therapy is non-invasive, does not have significant adverse effects, but is moderately costly.

E.12.p Ultrasound (Including Phonophoresis)

Ultrasound (Including Phonophoresis) is an accepted treatment. Ultrasound uses sonic generators to deliver acoustic energy for therapeutic thermal and/or non-thermal soft tissue effects. Indications include scar tissue, adhesions, collagen fiber and muscle spasm, and the need to extend muscle tissue or accelerate the soft tissue healing. Ultrasound with electrical stimulation is concurrent delivery of electrical energy that involves dispersive electrode placement. Indications include muscle spasm, scar tissue, pain modulation, and muscle facilitation.

Phonophoresis is the transfer of medication to the target tissue to control inflammation and pain through the use of sonic generators. These topical medications include, but are not limited to, steroidal anti-inflammatory and anesthetics.

- Time to produce effect: 6 to 15 treatments
- Frequency: 3 times per week
- Optimum duration: 4 to 8 weeks
- Maximum duration: 8 weeks

E.12.q Vertebral Axial Decompression (VAX-D)/DRX, 9000

Motorized traction devices which purport to produce non-surgical disc decompression by creating negative intradiscal pressure in the disc space include devices with the trade names of VAX-D and DRX 9000. There are no good studies to support their use. They are not recommended.

E.12.r Whirlpool/Hubbard Tank

Whirlpool/Hubbard Tank is a generally accepted treatment in which conductive exposure to water at varied temperatures that best elicits the desired effect. It generally includes massage by water propelled by a turbine or Jacuzzi jet system and has the same thermal effects as hot packs, if water temperature exceeds tissue temperature. It has the same thermal effects as cold application, if comparable temperature water is used. Indications include the need for analgesia, relaxing muscle spasm, reducing joint stiffness, and facilitating and preparing for exercise.

- Time to produce effect: 2 to 4 treatments
- Frequency: 3 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

E.13 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 maximum medical improvement. 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 and direction may aid the patient in decreasing stress and depression, and promote optimum rehabilitation.

F. Therapeutic Procedures - Operative

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

While sufficient time allowances for non-operative treatment are required to determine the natural cause and response to non-operative treatment of low back pain disorders, timely decision making for operative intervention is critical to avoid de-conditioning and increased disability (exclusive of "emergent" or urgent pathology such as cauda equina syndrome or associated rapidly progressive neurologic loss). In general, if the program of non-operative treatment fails, operative treatment is indicated when:

- 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 treatment, or at the end of longer duration of non-operative programs for debilitated patients with complex problems; and/or
- Frequent recurrences of symptoms cause serious functional limitations even if a non-operative active treatment program provides satisfactory relief of symptoms, and restoration of function on each recurrence.
- Mere passage of time with poorly guided treatment is not considered an active treatment program.

Surgical workup and implementation for simple decompression of patients with herniated nucleus pulposus and sciatica should occur within 6 to 12 weeks after injury at the latest, within the above stated contingencies. For patients with true, refractory mechanical low back pain in whom fusion is being considered, it is recommended that a decisive commitment to surgical or non-surgical interventions occur within 5 months following injury, at the latest.

Spinal decompression surgeries and fusion have re-operation rates of approximately 10% or more over the following five years. 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 sitting, standing, walking,

strength, endurance, 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. (Refer to section E.11.) Interdisciplinary interventions should be strongly considered post-operatively in any patient not making functional progress within expected time frames. (Refer to Interdisciplinary Programs, Section E. 5. b.)

Return to work restrictions should be specific according to the recommendations in Section E. 10, Return to Work. Most non-fusion surgical patients can return to a limited level of duty between 3 to 6 weeks. Full activity is generally achieved between 6 weeks to 6 months depending on the procedure and healing of the individual.

F.1 Discectomy

Description: To enter into and partially remove the disc.

Complications: Includes, but are not limited to, nerve damage, wrong level operation, spinal fluid leakage, infection, and hemorrhage.

Surgical Indications: To include all of the following: Primary radicular symptoms, radiculopathy on exam, correlating imaging study, and failure of non-surgical care. There is good evidence that surgery provides initial improvement of radicular symptoms with respect to chronic low back pain. There is conflicting evidence that the long-term outcome differs from that of the natural history of healing.

Operative Treatment: Partial discectomy and root decompression.

Post-Operative Therapy: A formal physical therapy program should be implemented post-operatively. Active treatment, which patients should have had prior to surgery, will frequently require a repeat of the sessions previously ordered.

F.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, and hematoma.

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.

Operative Treatment: Partial discectomy.

F.3 Laminotomy/Laminectomy/Foramenotomy/Facetectomy

Description: These procedures provide access to produce neural decompression by partial or total removal of various parts of vertebral bone.

Complications: Include but are not limited to, nerve injury, post-surgical instability, CSF leakage, and infection.

Surgical Indications: include all of the following: Primary radicular symptoms, radiculopathy on exam, correlating imaging study, and failure of non-surgical care.

Operative Treatment: Laminotomy, partial discectomy & root decompression.

Post-Operative Therapy: A formal physical therapy program should be implemented post-operatively. Active treatment, which patients should have had prior to surgery, will frequently require a repeat of the 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 3-6 weeks post-operatively. The goals of the therapy program should include instruction in a long-term home based exercise program. (Refer to Section E. 11, Active Therapy.)

F.4 Spinal Fusion

Description: Use of bone grafts, sometimes combined with metal devices, 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, graft extrusion and inpatient mortality. There is an increased likelihood of complications with instrumented fusion, although the majority are minor. There is some evidence that instrumented 360 degree fusions are most likely to involve major complications.

Surgical Indications: A timely decision-making process is recommended when considering patients for possible fusion. For chronic low back problems, fusion should not be considered within the first 5 months of symptoms, except for fracture or dislocation.

Although there is a statistical correlation between successful radiographic fusion and a good functional outcome, the relationship is not strong in the first two years. However, a recent observational study appears to indicate clinical deterioration in patients with unsuccessful radiographic fusion at an average of seven years post-operatively. There is good evidence that instrumented fusion, compared to non-instrumented fusion, produces a slightly better

radiographically-confirmed bony union, with small to moderate functional advantages. Studies of surgical procedures report higher rates of complications with instrumented fusion.

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 after one year. 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. Fusions associated with decompression are more likely to reduce leg pain.

Recombinant Human Bone Morphogenetic Protein (rhBMP-2) is 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 writing, rhBMP-2 is FDA approved for use in anterior lumbar interbody fusion (ALIF) 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. RhBMP-2 avoids the need for harvesting iliac crest donor bone and can therefore, avoid this complication of persistent pain. 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. At the time of this guideline writing, it is still investigational. Information concerning safe and effective dosing and application are being submitted to the FDA. All other applications are considered off-label and not FDA approved. 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. 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 (L2 - L4) 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.

Indications for spinal fusion may include:

1. Neural arch defect – Spondylolytic spondylolisthesis, congenital unilateral neural arch hypoplasia.
2. Segmental Instability - Excessive motion, as in degenerative spondylolisthesis, 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.

4. Revision surgery for failed previous operation(s) if significant functional gains are anticipated.
5. 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/Discography demonstrate disc pathology or spinal instability; and
4. Spine pathology is limited to two levels; and
5. Psychosocial evaluation with confounding issues addressed.

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 Therapy: Operative procedures may include: a) Intertransverse Fusion; 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 also performed; or d) Anterior/posterior (360?) Fusion – most commonly seen in unstable or potentially unstable situations or non-union of a previous fusion.

Post-operative Therapy: A formal physical therapy program should be implemented post-operatively. Active treatment, which patients should have had prior to surgery, will frequently require a repeat of the 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 core stabilization, strengthening, and endurance is recommended to be initiated once the fusion is solid and without complication. The goals of the therapy program should include instruction in a long-term home based exercise program. (Refer to section e.11, Active therapy).

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, light-to-medium work within 6 to 9 months post-operatively and medium-to-medium/heavy work within 6 to 12

months post-operatively. Patients requiring fusion whose previous occupation involved heavy-to-very-heavy labor should be considered for vocational assessment as soon as reasonable restrictions can be predicted. 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 6 months, the functional prognosis with or without fusion becomes guarded for that individual.

F.5 Sacroiliac Joint Fusion

Description: Use of bone grafts, sometimes combined with metal devices, to produce a rigid connection between two or more adjacent vertebrae providing symptomatic instability as a part of major pelvic ring disruption.

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.

F.6 Implantable Spinal Cord Stimulators

Implantable Spinal Cord Stimulators are reserved for those low back pain patients with pain of greater than 6 months duration who have not responded to the standard non-operative or operative interventions previously discussed within this document. Refer to Department's Chronic Pain Disorder Medical Treatment Guidelines.

F.7 Intradiscal Electrothermal Annuloplasty (IDEA) (more commonly called IDET, or Intradiscal Electrothermal therapy)

Description: An outpatient non-operative 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. Physicians performing this procedure must have been trained in the procedure and should have performed at least 25 prior discograms. Prior authorization is required for IDEA.

Complications: Complications include, but are not limited to, discitis, nerve damage, pain exacerbation, anaphylaxis, probe breakage, and disc herniation.

Surgical Indications: Failure of conservative therapy including physical therapy, medication management, or therapeutic injections. Indications may include those with chronic low back pain, disc related back pain, or pain lasting greater than 6 months. There is conflicting evidence regarding its effectiveness. In one of the most recent studies only approximately 40% of patients had greater than 50% relief of pain. Patients should be aware of these percentages. Strict

adherence to the indications is recommended. Only patients who meet the following should be considered, including:

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/Discography demonstrate disc pathology; and
4. Spine pathology is limited to two levels; and
5. Psychosocial evaluation with confounding issues addressed.
6. For any potential surgery, 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:

1. Age not above 60 or under 18; and
2. Normal neurological exam; and
3. No evidence of nerve root compression on MRI; and
4. Concordant pain reproduced with provocation discography at less than 1ml dye volume (low pressure); and
5. Functionally limiting low back pain far in excess of leg pain for at least 6 months; and
6. No evidence of inflammatory arthritis, spinal conditions mimicking low back pain, moderate to severe spinal stenosis, spinal instability, disc herniation, or medical or metabolic diseases precluding follow-up rehabilitation; and
7. Disc height greater than 50% of adjacent normal disc; and
8. No previous IDET procedure at the same level.

Operative Treatment: A wire is guided into the identified painful disc using fluoroscopy and then the wire is heated within the disc.

Post-Procedure Therapy: Some cases may require epidural injection after the IDET procedure has been performed. A corset should be used for the first 6 weeks. Sitting upright is limited to 30 to 45 minutes for the first two weeks. A formal physical therapy program should be implemented post-operatively. Some patients may benefit from several occupational therapy visits to improve performance of ADLs. Rehabilitation may take as long as 6 months and include stretching during the first month, floor exercises in the second month, 3 to 5 consecutive months of progressive exercise program, and sport activities in the 5th and 6th months as tolerated. The goals of the therapy program should include instruction in a long-term home-based exercise program. (Refer

to Section E.11 Active Therapy).

Return to Work: Barring complications, may be able to return to limited duty after one to two weeks. A corset should be used for the first six weeks. Sitting upright is limited to 30 to 45 minutes for the first two weeks. Zero to 10 pounds lifting limits for first 6 weeks post-procedure. If successful, patients may return to medium work category (20 to 50 pounds per DOT standards) at 4 to 6 months.

F.8 Laser Discectomy

Laser Discectomy involves the delivery of laser energy into the center of the nucleus pulposus using a 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.

F.9 Artificial Disc Replacement

Description: 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 range of motion.

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.

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.

Complications:

- 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

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
- Psychosocial evaluation with confounding issues addressed

Contraindications:

- Significant spinal deformity/scoliosis
- Facet joint arthrosis
- Spinal instability
- Deficient posterior elements
- Infection
- Previous spinal surgery at a different level
- 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
- Osteoporosis or any metabolic bone disease
- Chronic steroid use or use of other medication known to interfere with bone or soft tissue healing
- Autoimmune disorder
- 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

Post-operative Therapy: Bracing may be appropriate. A formal physical therapy program should be implemented post-operatively. Active treatment, which patients should have had prior to surgery, will frequently require a repeat of the 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 Section E. 11, Active Therapy.)

F.10 Kyphoplasty

Description: 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. Vertebral height correction is inconsistent, with approximately 35% to 40% of procedures failing to restore height or kyphotic angle.

Complications: Cement leakage occurs in approximately 9% 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: Kyphoplasty is an accepted treatment for the following indications:

- Compression fracture
- Vertebral height loss between 20% and 85%
- Vertebral height restoration. Kyphoplasty is more likely to increase vertebral height if performed within 30 days of fracture occurrence

Contraindications:

- 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, and
- Coagulopathy

F.11 Vertebroplasty

Description: a procedure for the treatment of painful thoracic and lumbar vertebral compression fractures caused by osteoporosis or other metabolic bone disease. Polymethylmethacrylate (PMMA) bone cement is injected with high pressure into the vertebral body via an 11- to 13-gauge needle, with the goal of stabilizing the spine and relieving pain. The procedure does not correct spinal deformity. Pain relief can be expected in approximately 90% of patients. Vertebral height correction is inconsistent, with approximately 35% to 40% of procedures failing to restore height or kyphotic angle.

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. Cement leakage alone occurs in approximately 40% of vertebroplasties.

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

Indications:

- Compression fracture of preferably less than 30 days
- Vertebral height loss between 20% and 85%
- Intact posterior wall

Contraindications:

- 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); and
- Infection; and
- Coagulopathy

F.12 Percutaneous Radiofrequency Disc Decompression

Percutaneous Radiofrequency Disc Decompression is an investigational procedure which 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.

F.13 Nucleus Pulposus Replacement

Nucleus Pulposus 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.

F.14 Epiduroscopy and Epidural Lysis of Adhesions

(Refer to Section E. 3, Injections-Therapeutic).

F.15 Intraoperative Monitoring

Intraoperative 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 may be used to evaluate spinal cord integrity and screw placement during the operative procedure. The use of intraoperative monitoring can be anticipated to become more common as percutaneous spinal procedures gain greater acceptance.