DEPARTMENT OF LABOR

Division of Industrial Affairs
The Office of Workers' Compensation

Health Care Practice Guidelines

PART D Low Back Treatment Guidelines

1.0 Introduction

1.1 Pursuant to 19 **Del.C.** §2322C, health care practice guidelines have been adopted and recommended by the Workers' Compensation Oversight Panel to guide utilization of health care treatments in workers' compensation including, but not limited to, care provided for the treatment of employees by or under the supervision of a licensed

health care provider, prescription drug utilization, inpatient hospitalization and length of stay, diagnostic testing, physical therapy, chiropractic care and palliative care. The health care practice guidelines apply to all treatments provided after the effective date of the regulation adopted by the Department of Labor, May 23, 2008, and regardless of the date of injury.

1.2 The guidelines are, to the extent permitted by the most current medical science or applicable science, based on well-documented scientific research concerning efficacious treatment for injuries and occupational disease. To the extent that well-documented scientific research regarding the above is not available at the time of adoption of the guidelines or is not available at the time of any revision to the guidelines, the guidelines have been and will be based upon the best available information concerning national consensus regarding best health care practices in the relevant health care community.

1.3 The guidelines, to the extent practical and consistent with the Act, address treatment of those physical conditions which occur with the greatest frequency, or which require the most expensive treatments, for work-related injuries based upon currently available Delaware data.

1.4 Services rendered by any health care provider certified pursuant to 19 **Del.C.** §2322D(a) to provide treatment or services for injured employees shall be presumed, in the absence of contrary evidence, to be reasonable and necessary if such treatment and/or services conform to the most current version of the Delaware health care practice guidelines.

1.5 Services rendered outside the Guidelines and/or variation in treatment recommendations from the Guidelines may represent acceptable medical care, be considered reasonable and necessary treatment and, therefore, determined to be compensable, absent evidence to the contrary, and may be payable in accordance with the Fee Schedule and Statute, accordingly.

1.6 Services provided by any health care provider that is not certified pursuant to 19 **Del.C.** §2322D(a) shall not be presumed reasonable and necessary unless such services are pre-authorized by the employer or insurance carrier, subject to the exception set forth in 19 **Del.C.** §2322D(b).

1.7 Treatment of conditions unrelated to the injuries sustained in an industrial accident may be denied as unauthorized if the treatment is directed toward the non-industrial condition unless the treatment of the unrelated injury is rendered necessary as a result of the industrial accident.

1.8 The Workers' Compensation Oversight Panel and Department of Labor recognized that acceptable medical practice may include deviations from these Guidelines, as individual cases dictate. Therefore, these Guidelines are not relevant as evidence of a provider's legal standard of professional care.

1.9 In accordance with the requirements of the Act, the development of the health care guidelines has been directed by a predominantly medical or other health professional panel, with recommendations then made to the Workers' Compensation Oversight Panel.

2.0 General Guideline Principles

2.1 Application of Guidelines. The Department provides procedures to implement medical treatment guidelines and to foster communication to resolve disputes among the provider, payer, and patient through the Workers' Compensation Rules of Procedure.

2.2 Education. Education of the patient and family, as well as the employer, insurer, policy makers and the community should be the primary emphasis in the treatment of chronic pain and disability. Currently, practitioners often think of education last, after medications, manual therapy, and surgery. Practitioners must implement strategies, to educate patients, employers, insurance systems, policy makers, and the community as a whole. An education-based paradigm should always start with inexpensive communication providing reassuring and evidence-based information to the patient. More in-depth patient education is currently a component of treatment regimes which employ functional restorative, preventive, and rehabilitative programs. No treatment plan is complete without addressing issues of individual or group patient education as a means of facilitating self-management of symptoms and prevent.

2.3 Informed Decision Making. Providers should implement informed decision making as a crucial element of a successful treatment plan. Patients, with the assistance of their health care practitioner, should identify their personal and professional functional goals of treatment at the first visit. Progress towards the individual's identified functional goals should be addressed by all members of the health care team at subsequent visits and throughout the established treatment plan. Nurse care managers, physical therapists, and other members of the health care team play an integral role in informed decision making and achievement of functional goals. Patient education and informed decision making should facilitate self-management of symptoms and prevention of further injury.

2.4 Treatment Parameter. With respect to Therapy (Active or Passive), time frames/visits 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 comorbidities and availability of services. Clinical judgment may substantiate the need to accelerate or decelerate modify the time frames total number of visits discussed in this document. The majority of injured workers with low back pain often will achieve resolution of their condition within 8 to 24 visits (*Guide to Physical Therapy Practice* – Second Edition). It is anticipated that most injured workers will not require the maximum number of visits described in these guidelines. They are designed to be a ceiling and care extending beyond the maximum allowed visits may warrant utilization review.

2.5 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. All rehabilitation programs must incorporate "Active Interventions" no later than 12 visits 3 weeks after the onset of treatment. Reimbursement for passive modalities only after the first 12 visits 3 weeks of treatment without clear evidence of Active Interventions will require supportive documentation.

2.6 Active Therapeutic Exercise Program goals should incorporate patient strength, endurance, flexibility, coordination, and education. This includes functional application in vocational or community settings.

2.7 Positive Patient Response results are defined primarily as functional gains that can be objectively measured. Objective functional gains include, but are not limited to, positional tolerances, range of motion (ROM), strength, endurance, activities of daily living, cognition, 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.

2.8 Re-evaluate Treatment Every 10 to 12 Treatments. With respect to Therapy (Active or Passive), if a given treatment or modality is not producing positive results within 10 to 12 treatments, the treatment may be either modified or discontinued. Before discontinuing the treatment, the provider should have a detailed discussion with the patient to determine the reason for failure to produce positive results. Reconsideration of diagnosis should also occur in the event of poor response to a seemingly rational intervention.

2.9 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.

2.10 Six-Month Time Frame. The prognosis drops precipitously for returning an injured worker to work once the injured worker has been temporarily totally disabled for more than 6 months. The emphasis within these guidelines is to move patients along a continuum of care and return to work within a 6-month time frame, whenever possible. It is important to note that time frames may not be pertinent to injuries that do not involve work-time loss or are not occupationally related.

2.11 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 6 months. The patient should be educated regarding the benefits of return to work, work restrictions and follow-up if problems arise.

2.11.1 Employers should be encouraged 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.

2.11.2 Due to the large spectrum of injuries of varying severity and varying physical demands in the workplace, it is not possible to make specific return to work guidelines for each injury.

2.12 Guideline Recommendations and Inclusion of Medical Evidence. Recommendations are based on available evidence and/or consensus recommendations of the standard of care within Delaware. Those procedures considered inappropriate, unreasonable, or unnecessary are designated in the guideline as being “not recommended.”

2.13 Delayed Recovery. Strongly consider a psychological evaluation, if not previously provided, as well as interdisciplinary rehabilitation 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, even despite optimal care, 3-10% of all industrially injured patients will not recover within the time lines outlined in this document. 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.

3.0 Overview of Care

3.1 Low back pain is a ubiquitous condition with a lifetime prevalence of 84% and a high recurrence rate. However, only about 15% of the population has severe pain with functional/disability limitations. Thus, the expectation is that most low back pain will respond to therapy and self-management, and not require invasive measures.

3.2 Low Back Pain Without Radicular Pain or Neurologic Findings. Multiple studies confirm the importance of the first visit and the need to follow a specific process in caring for the most common low back pain patients. It is important to perform a thorough neurological evaluation to clarify a specific diagnosis. Initial treatment should be similar to all low back pain patients who do not have progressive neurologic deficits or “red flag” signs, such as cauda equina syndrome, foot drop, or evidence of epidural abscess. Back strains as well as disc herniations and spinal stenosis aggravations with progressive neurological findings can initially be treated conservatively. However, those with any radicular findings will require close follow up and repeated neurological examinations. Refer to Section 3.3 Low Back Pain with Radicular Pain and Other Neurological Findings.

3.2.1 A careful and detailed history and neurological exam should be done at the initial visit and repeated periodically to assess for any signs of progressive or continuing weakness, or myelopathy. All care begins with patient education and presentation of treatment options for informed decision making. In the absence of “red flag” findings or objective motor deficits, there is normally no need for surgery until after 6 weeks of conservative care has failed to result in adequate functional gains. At the first visit, patients with a benign clinical team should understand the high likelihood that their condition will improve over several weeks with return to activity and some pain management. It is essential that continual neurologic exams be completed regularly to rule out disc herniations and stenosis with accompanying neurologic

findings.

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

3.2.3 Health care providers are expected to discuss self-management of pain with their patients. Appropriate over-the-counter mediation and ice or heat, if desired by the patient may initially be helpful. If pain is severe, as in some cases with ruptured discs, opioids may be prescribed for a short time period. This avoids the accumulation of unused opioids that may be available for others in the household to misuse and minimizes the likelihood of opioid dependence. Multiple repeat prescriptions for opioids should generally be avoided. If it is necessary to prescribe opioids for more than 14 days, the provider should do the following:

3.2.3.1 Repeat a thorough neurologic and back examination to rule out a more serious diagnosis;

3.2.3.2 Check the Physician’s Drug Monitoring Program (PDMP);

3.2.3.3 Consider urine drug screening;

3.2.3.4 Follow the patient closely; and

3.2.3.5 Consider a short screening questionnaire for abuse risk before prescribing.

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

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

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

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

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

3.2.8 Spinal injections should not be done without prior imaging to establish the diagnosis. The risks versus benefits must be carefully weighed and discussed with the patient when these interventions are considered. Both the specialist referred to and the authorized provider must thoroughly discuss and document the possible complications, the limited short-term benefits, and the need for continuing engagement in active therapy.

Imaging is recommended prior to a spinal injection or to rule out other acute diagnoses such as fracture, occult cancer, infection, upper extremity weakness, signs of myelopathy, radiculopathy or suspected compression fracture. If a patient has persistent pain and imaging is deemed necessary, the ordering provider should document elements from face-to-face discussion with the patient.

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

3.3 Low Back Pain with Radicular and Other Neurological Findings. Radicular findings from a herniated disc with progressive neurological findings, cauda equina symptoms, or without obvious significant continuing weakness should be treated according to the following sections. Seventy percent of patients with radicular pain and non-surgical treatment are likely to have marked reduction in pain at 4 weeks with a 60% return to work. After 8 months, over 90% would be expected to have an excellent outcome and return to work. About 20% will have a recurrence of symptoms.

3.3.1 Patients with disc herniation and associated foot drop or cauda equina syndrome require early imaging and surgical intervention. Any patient with neurologic findings of significant weakness or significant functional impairment at 6 weeks should be considered for surgical referral.

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

4.0 Initial Diagnostic Procedures

4.1 The Division of Industrial Affairs 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.

4.2 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. The history should include:

4.2.1 Mechanism of Injury. This includes details of symptom onset and progression, including a detailed description and the position of the body before, during, and at the end of the incident. In the absence of a known specific incident, common positioning of the body during the workday and frequency of requirements such as lifting, pushing, and pulling should be included.

4.2.2 Description of Pain. This may include location of pain, nature of symptoms, and alleviating/exacerbating factors (e.g., sleep positions, sitting tolerance). The presence of pain at night or while at rest may be a sign of more extensive pathology. The history should include both the primary and secondary complaints (e.g., primary low back pain, secondary hip, or groin). Pain should be quantified on a Visual Analog Scale (VAS) or similar accepted pain scale. Screening the patient for fear-avoidance issues_regarding recurrent pain may be useful initially to guide treatment.

4.2.3 Functional Assessment. Functional ability should be assessed and documented at the beginning of treatment. Periodic assessment should be recorded throughout the course of care to follow the trajectory of recovery. In addition to being more relevant to recovery from low back pain, functional measures are likely to be more reliable over them than pain measures.

4.2.4 Presence and distribution of lower extremity numbness, paresthesia, or weakness, especially if precipitated by coughing or sneezing.

4.2.5 Alteration in bowel, bladder, or sexual function; and for female patients, alternation in their menstrual cycle.

4.2.6 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

4.2.7 Ability to perform job duties and activities of daily living (ADLs) including the ability to maintain balance and walk rapidly without difficulty.

4.3 Past History

4.3.1 Past medical history including neoplasm, gout, arthritis, hypertension, diabetes, and fractures;

4.3.2 Review of systems includes symptoms of rheumatologic, neurologic, endocrine, neoplastic, infections, and other systemic diseases;

4.3.3 Type 1 or Type 2 diabetes. People with a body-mass index (BMI) greater than 30 may be at risk for the disease;

4.3.4 Smoking History. Smoking appears to be related to low back pain and may predispose patients to opioid addiction;

4.3.5 Medication Use. Prescription and non-prescription including vitamins and natural products;

4.3.6 Vocational and recreational pursuits, including military service; and

4.3.7 History of depression, anxiety, or other psychiatric illness.

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

4.4.1 General inspection, including stance and gait;

4.4.2 Visual inspection;

4.4.3 Palpation;

4.4.4 Lumbar range of motion;

4.4.5 Nerve tension testing. Both the straight leg raising test and the slump test can be used to reproduce symptoms and are highly reproducible and correlated. Symptoms usually occur at around 50 degrees of flexion and are exacerbated by ankle dorsiflexion. The slump test is a straight leg raise performed with the patient in a seated slumped forward posture, neck flexed and arms behind the back. A positive contralateral straight leg raising is quite specific, although less sensitively for disc herniation;

4.4.6 Motor and sensory examination of the lower extremities with specific nerve roof focus;

4.4.7 Deep tendon reflexes with or without Babinski's;

4.4.8 Assessment of gait, rapid walking, and balance;

4.4.9 A combination of multiple physical exam test results is preferred as none are independently diagnostic;

4.4.10 If applicable to injury, anal sphincter tone or perianal sensation; and

4.4.11 If applicable, abdominal examination, vascular examination, circumferential lower extremity measurements, or evaluation of hip or other lower extremity abnormalities.

4.5 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. Specific indications for the radiograph should be listed on the request form to aid the radiologist and x-ray technician. Suggested indications may include:

4.5.1 History of significant trauma, especially blunt trauma or fall from a height;

4.5.2 Age over 55 years;

4.5.3 Unexplained or persistent low back pain for at least 6 weeks or pain that is worse with rest;

4.5.4 Localized pain, fever, constitutional symptoms, or history or exam suggestive of intravenous drug abuse, prolonged steroid use, or osteomyelitis;

4.5.5 Suspected lesion in the lumbosacral spine due to systemic illness such as a rheumatic/rheumatoid disorder or endocrinopathy. Suspected lesions may require special views;

4.5.6 Past medical history suggestive of pre-existing spinal disease, osteoporosis, spinal instrumentation, or cancer; and

4.5.7 Prior to high-velocity/low amplitude manipulation or Grade IV to V mobilization.

4.6 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:

4.6.1 Complete blood count (CBC) with differential can detect infection, blood dyscrasias, and medication side effects;

4.6.2 Blood-glucose level, which can be used to detect evidence of Type 1 or Type 2 diabetes;

4.6.3 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;

4.6.4 Serum calcium, phosphorous, uric acid, alkaline phosphatase, and acid phosphatase can detect metabolic bone disease;

4.6.5 Urinalysis for bacteria (usually with culture and sensitivity), calcium, phosphorus, hydroxyproline, or hematuria; and

4.6.6 Liver and kidney function may be performed for prolonged anti-inflammatory use or other medications requiring monitoring.

5.0 Follow-Up Diagnostic Imaging and Testing Procedures

5.1 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.

5.2 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.

5.3 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, or the treating practitioner's familiarity with the procedure.

5.4 Imaging studies are generally accepted, well-established and widely used diagnostic procedures. In the absence of myelopathy, or progressive neurological changes, or neurologic deficit, or history of cancer, imaging usually is not appropriate until conservative therapy has been tried and failed. Four to 6 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, a careful neurological exam or referral may be appropriate, and the clinical findings should have preference.

5.4.1 There is some evidence that degenerative changes occurring over time in asymptomatic workers effect the cervical and lumbar spine equally. Small herniations and protrusions may not be pain generators, although small foraminal disc herniations are likely

to compress the nerve root and require surgical removal. Moderate reduction in the cross-sectional area of the spinal cord may be see without myelopathy in the majority of patients older than 40; therefore, clinical correlation is required.

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

5.4.2 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 implanted device; however, MRI scanners compatible with pacemakers are now available.

5.4.2.1 In general, conventional full-size, high field magnet 1.5 tesla, MRI provides better resolution and is preferred. A lower field scan may be indicated when a patient cannot fit into a high field scanner or 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 or radiologist.

5.4.2.2 Specialized MRI Scans:

5.4.2.2.1 MRI with 3-dimensional Reconstruction. On rare occasions, MRI with 3-dimenational 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.

5.4.2.2.2 Dynamic-kinetic MRI of the Spine. Dynamic-kinetic MRI of the spine uses an MRI unit configured with a top-front open design that 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 it is not recommended until the correlation with clinical syndromes is firmly established.

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

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

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

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

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

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

5.4.8 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 and is usually not used for the lumbar spine.

5.4.9 Dynamic [Digital] Fluoroscopy. Dynamic [Digital] Fluoroscopy of the lumbar spine measures the motion of intervertebral segments using a video fluoroscopy 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.

5.5 Other Tests. The following diagnostic procedures in this subsection 5.5 are listed in alphabetical order, not by importance:

5.5.1 Electrodiagnostic Testing

5.5.1.1 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. However, F-Wave Latencies are not diagnostic for radiculopathy. H-reflex Studies are of value regarding the S-1 radiculopathy.

5.5.1.1.1 In general, EMG and NCS are complementary to imaging procedures such as CT, MRI, and/or myelography or diagnostic injection procedures.

5.5.1.1.2 Electrodiagnostic studies may provide useful, correlative neuropathophysiological information that would be otherwise unobtainable from the radiologic studies discussed above and can assist in treatment decisions, such as the need for surgery.

5.5.1.2 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.

5.5.1.3 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.

5.5.1.4 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.

5.5.1.5 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.

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

5.5.1.6.1 These tests are designed to detect differences between persons with and without low back pain, measuring signals in lumbar flexion which show that painful paraspinal muscles fail to relax fully. It may show aspects of the pathophysiology of muscle activity which advance the scientific understanding of

low back pain. Some versions of this test also purport to determine the significance of disc pathology and the age of an injury. It has not been evaluated in a setting with a spectrum of patients commonly seen in clinical practice and tested against a diagnostic reference standard.

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

5.5.2 Injections — Diagnostic

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

5.5.2.1.1 There is some evidence that the addition of steroids to a transforaminal bupivacaine injection may reduce the frequency of surgery in the first year after treatment in patients with neurologic compression and corresponding imaging findings who also are strong candidates for surgery and have completed 6 weeks of therapy without adequate benefit. There is some evidence that the benefits for the non-surgical group persisted for at least 5 years in most patients, regardless of the type of block given.

5.5.2.1.2 An additional study provides some evidence that after 6 weeks of conservative therapy for large, herniated discs, an epidural injection may be attempted, as it does not compromise the results of a discectomy at a later date. One half o the patients in this study who were randomized to ESIs did not have surgery and this benefit persisted. Because this study did not have a control group that received neither treatment, nor a group which received injections without steroids, one cannot make definite conclusions regarding the efficacy of ESI injections in this setting.

5.5.2.2 Indications. Since these procedures are invasive, less invasive or non-invasive procedures should be considered first. All spinal injections should be preceded by either an MRI or a CT scan. Selection of patients, choice of procedure, and localization of the level for injection should be determined by clinical information indicating strong suspicion for pathologic condition from reproducible exam findings. Diagnostic blocks may be helpful when MRI or other diagnostic tests are not definitive. The number of diagnostic procedures should be limited in any individual patient to those most likely to be primary pain generators. Patients should not receive all of the diagnostic blocks listed merely in an attempt to identify 100% of the pain generators.

5.5.2.3 The interpretation of the test results is 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. 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.

5.5.2.4 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. Injection of contrast dye to assure correct needle placement is required to verify the flow of medication. Permanent images are required to verify needle placement. Unnecessary fluoroscopy procedure should be avoided due to the radiation exposure contributing to cancer risk. The subspecialty disciplines of the physicians performing the injections may be varied, including: 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 with interventional training. They must also be knowledgeable in radiation safety and credentialed by a hospital or surgery center.

5.5.2.5 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.

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

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

5.5.2.5.1.2 Indications. They may be used for patients who are having significant pain that is interfering with daily functions and the active therapy necessary for recovery despite medical pain management and active therapy. All injections should be preceded by an MRI or CT scan.

5.5.2.5.1.3 The following sets of patients may have epidural injections may be considered with the following diagnosis:

5.5.2.5.1.3.1 When a patient with radicular findings due to herniated disc, and has had approximately 4-6 weeks post active therapy, 1 epidural may be attempted at the patient's discretion.

5.5.2.5.1.3.2 For rare, acute ruptured (herniated) disc with clear objective radiculopathy if, after 1 to 2 weeks of initial oral analgesic and conservative treatment; the patient:

5.5.2.5.1.3.2.1 Has continued pain interfering with most activities of daily living (ADL) functions; and/or

5.5.2.5.1.3.2.2 is unable to tolerate the requirement movements to participate in therapy; and/or

5.5.2.5.1.3.2.3 has pain greater in the leg than in the back, generally of 7 or greater on a VAS scale of 10; and/or

5.5.2.5.1.3.2.4 has pain following a correlated radicular dermatome; and/or

5.5.2.5.1.3.2.5 there is a herniated disc on the MRI at the level of subjective and objective findings; and has either:

5.5.2.5.1.3.2.5.1 dural tension signs of straight leg raising or slump test resulting in radicular symptoms correlating with imaging pathology, and/or

5.5.2.5.1.3.2.5.2 one of the following documented, reproducible findings, which correlates with the suspected nerve root impingement;

5.5.2.5.1.3.2.5.3 decreased reflexes, or

5.5.2.5.1.3.2.5.4 radicular sensation deficits, or

5.5.2.5.1.3.2.5.5 motor weakness on testing.

5.5.2.5.1.4 Spinal Stenosis Patients

5.5.2.5.1.4.1 Patients with radicular findings: When the patient has document spinal stenosis, has completed 4-6 weeks of active therapy, has persistent radicular findings and difficulty with some activities, thus meeting criteria for surgical intervention, the patient may have one diagnostic injection. Because stenosis is not likely to change anatomically, unlike herniated discs which recede overtime, and due to the success rate of surgery for this condition in most cases, early surgical consultation is encouraged whenever the patient remains symptomatic after conservative therapy. If the patient does not wish to have a surgical intervention 2 additional injections may be provided if the original diagnostic intervention was successful per guideline standards.

5.5.2.5.1.4.2 Patients with claudication: The patient has documented spinal stenosis, has completed 4-6 weeks of active therapy, has persistent claudication symptoms and difficulty with some activities, thus meeting criteria for surgical intervention. The patient may have 1 diagnostic injection. Patients would have any objective neurologic findings should proceed as the above patient with radicular findings for whom an early surgical consultation is recommended. There is some evidence that translaminar steroid injections do not increase walking tolerance for those with spinal stenosis compared to local anesthetic. Those who have mild claudication, or moderate or severe claudication and who do not desire surgery, may continue to receive up to 2 additional injections if the original diagnostic intervention was successful per guideline standards.

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

5.5.2.5.2 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).

5.5.2.5.2.1 To be a positive diagnostic block, the patient should report a reduction of pain of 50% or greater relief from baseline or the length of time appropriate for the local anesthetic used.

5.5.2.5.2.2 It is obligatory that sufficient data be accumulated by the examiner performing this procedure such that the value of the procedure is evidence to other reviewers. This entails documentation of patient response regarding the degree and type of response to specific symptoms. To be successful the results should occur within the expected time frame and there should be pain relief of approximately 50% demonstrated by pre and post pain scores as measured by accepted pain scales (such as VAS). Examples of functional changes include reaching and lifting. Additionally, a prospective patient completed pain diary may be recorded that documents response hourly until the block has clearly worn off. The diary results should be compared to the expected duration of the local anesthetic phase of the procedure. Responses must be identified as to specific body part. The practitioner must identify the local anesthetic used and the expected duration of response for diagnostic purposes.

5.5.2.5.2.3 A separate comparative block on a different date may 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.

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

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

injection must be rigorously adhered to in order to correctly interpret the results of the diagnostic injection.

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

5.5.2.5.2.6 Frequency and maximum duration: May be repeated once for comparative blocks. Limited to 4 anatomic levels.

5.5.2.5.3 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 occur within the expected timeframe and there should be pain relief of approximately 50% demonstrated by pre and post pain scores as measured by accepted pain scales (such as VAS). Examples of functional changes include reaching and lifting.

Frequency and maximum duration: Once per suspected level. Limited to three levels. May be repeated once for confirmation.

5.5.2.5.4 Zygapophyseal (Facet) Blocks

Facet blocks are generally accepted. They may be used diagnostically to direct functional rehabilitation programs. A positive diagnostic block should result in a positive diagnostic functional benefit and an 50% 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.

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

5.5.2.5.4.2 Frequency and maximum duration: Once per suspected level, limited to 3 levels unilaterally or bilaterally at each session. If radiofrequency neurotomy is being considered, refer to the medical branch block section. May be repeated for confirmation.

5.5.2.5.5 Sacroiliac Joint Injection

5.5.2.5.5.1 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.

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

5.5.2.5.5.3 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 at least 50% pain relief (as measured by accepted pain scales such as a ~~VAS)~~ VAS).

5.5.3 Frequency and maximum duration: May be repeated for confirmation. Provocation Discography

5.5.3.1 Description. Discography is an accepted 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. 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.

5.5.3.2 Indications. Discography may be indicated when a patient has a history of

functionally limiting, unremitting low back pain of greater than ~~four~~ 4 months duration, with or without leg pain, which has been unresponsive to all conservative interventions. A patient who would not consider operative therapeutic intervention is not a candidate for an invasive non-therapeutic intervention, such as provocation discography.

5.5.3.2.1 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.

5.5.3.2.2 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.

5.5.3.2.3 Discography 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.

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

5.5.3.3.1 A patient with functionally limiting, unremitting back and/or leg pain of greater than ~~four~~ 4 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.

5.5.3.3.2 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).

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

5.5.3.4 Special Considerations

5.5.3.4.1 The procedure should be carried out by an experienced individual who has received specialized training in the technique of provocation discography.

5.5.3.4.2 Discography should be performed in a blinded format that avoids leading the patient with anticipated responses. The procedure should include 1 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.

5.5.3.4.3 Sterile technique must be utilized.

5.5.3.4.4 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.

5.5.3.4.5 The discography should be performed using a manometer to record pressure.

5.5.3.4.6 Intradiscal injection of local anesthetic may be carried out after the

provocation portion of the examination and the patient's response.

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

5.5.3.5 Reporting of Discography. In addition to a narrative report, the discography report should contain a standardized classification of disc morphology, the pain response, and 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, and surgery is being considered, 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.

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

5.5.3.5.1.1 Grade 0 = Normal Nucleus.

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

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

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

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

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

5.5.3.5.2 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.

5.5.3.5.2.1 Unequivocal Discogenic Pain

5.5.3.5.2.1.1 Stimulation of the target disc reproduces concordant pain.

5.5.3.5.2.1.2 The pain is registered as at least 6 on a 10-point VAS.

5.5.3.5.2.1.3 The pain is reproduced at a pressure of less than 15 psi above opening pressure; and

5.5.3.5.2.1.4 Stimulation of two adjacent discs does not produce pain at all.

5.5.3.5.2.2 Definite Discogenic Pain

5.5.3.5.2.2.1 Stimulation of the target disc reproduces concordant pain.

5.5.3.5.2.2.2 The pain is registered as at least 6 on a 10-point VAS.

5.5.3.5.2.2.3 The pain is reproduced at a pressure of less than 15 psi above opening pressure; and

5.5.3.5.2.2.4 Stimulation of at least one adjacent disc does not produce pain at all.

5.5.3.5.2.3 Highly Probable Discogenic Pain

5.5.3.5.2.3.1 Stimulation of the target disc reproduces concordant pain.

5.5.3.5.2.3.2 That pain is registered as at least 6 on a 10-point VAS.

5.5.3.5.2.3.3 That the pain is reproduced at a pressure of less than 50 psi above opening pressure; and

5.5.3.5.2.3.4 Stimulation of two adjacent discs does not produce pain at all.

5.5.3.5.2.4 Probable Discogenic Pain

5.5.3.5.2.4.1 Stimulation of the target disc reproduces concordant pain.

5.5.3.5.2.4.2 That pain is registered as at least 6 on a 10-point VAS.

5.5.3.5.2.4.3 The pain is reproduced at a pressure of less than 50 psi above opening pressure; and

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

5.5.3.5.2.4.5 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 probably 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.

5.5.4 Thermography is an accepted and established procedure, but has no use as a diagnostic test for low back pain and is not recommended.

6.0 Personality/Psychological/Psychosocial Evaluation

6.1 Generally accepted and well-established diagnostic procedures with selective use in the acute lumbar spine injury population and more widespread use in sub-acute and chronic lumbar spine populations.

6.2 These diagnostic testing procedures may be useful for patients with symptoms of depression, delayed recovery, chronic pain, recurrent painful conditions, disability problems, and for preoperative 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.

6.3 Formal psychological or psychosocial evaluation may consider 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. In addition to the customary initial exam, the evaluation of the injury worker should specifically address the following areas:

6.3.1 Employment history;

6.3.2 Interpersonal relationships, both social and work;

6.3.3 Leisure activities;

6.3.4 Current perception of the medical system;

6.3.5 Results of current treatment;

6.3.6 Perceived locus of control; and

6.3.7 Childhood history, including abuse and family history of disability.

6.4 Results should provide clinicians with a better understanding of the patient, thus allowing for more effective rehabilitation. The evaluation will determine the need for further psychosocial interventions, and in those cases, a Diagnostic Statistical Manual of Mental Disorders (DSM) diagnosis should be determined and documented. An individual with a PhD, PsyD, or Psychiatric MD/DO credentials should perform initial evaluations, which are generally completed within 1 to 2 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 test procedures as outlined in the Division's Chronic Pain Disorder Medical Treatment Guidelines.

6.5 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 2 hours of professional time.

7.0 Special Tests

7.1 These are generally well-accepted tests and are performed as part of a skilled assessment of the patients' capacity to return to work, their strength capacities, and physical work demand classifications and tolerance. The procedures in this Section 7.0 are listed in alphabetical order, not by importance.

7.2 Computer-Enhanced Evaluations. These may include isotonic, isometric, isokinetic, or isoinertial measurement of movement; range of motion (ROM); 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: 1 time for evaluation, 1 for mid-treatment assessment, and 1 at final evaluation.

7.3 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 stimulation tasks until the patient can tolerate a full workday.

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

7.3.1 Length of visit: Up to 8 hours/day.

7.3.2 Frequency: 2 to 5 visits per week.

7.3.3 Maximum duration: 8 weeks.

7.3.4 Participation in a program beyond 6 weeks must be documented with respect to need and the ability to facilitate positive symptomatic or functional gains.

7.4 Functional Capacity Evaluation (FCE). This 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 statis), postural tolerance, specific range of motion (ROM), coordination and strength, worker habits, employability, as well as psychosocial aspects of competitive employment may be evaluated. Reliability of patient reports and overall effort during testing is also reported. Components of this evaluation may include: musculoskeletal screen; cardiovascular profile/aerobic capacity; coordination; lift/carrying analysis; job specific activity tolerance; maximum voluntary effort; pain assessment/psychological screening; and non-material and material handling activities. Standardized national guidelines (such as National Institute of Occupational Safety and Health (NIOSH)) should be used as the basis for FCE recommendations.

7.5 Jobsite Evaluation. A comprehensive analysis of the physical, mental, and sensory components of a specific job may be beneficial in certain circumstances. These components may include: postural tolerance (statis and dynamic); aerobic requirements; ROM: torque/force; lifting/carrying; cognitive demands; social interactions; visual perceptual; sensation; coordination; environmental factors of a job; repetitiveness; and essential job functions. 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.

8.0 Therapeutic Procedures – Non-Operative

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

8.1.1 First, patients undergoing therapeutic procedure(s) are encouraged to return to modified or restricted duty during their rehabilitation at the earliest appropriate time. Refer to "Return-to-Work" in this Section 8.0 for detailed information.

8.1.2 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.

8.1.3 Third, providers should provide and document education to the patient. Before diagnostic tests or referral for invasive treatment take place, the patient should be able to clearly articulate the goals of the intervention, the general side effects and associated risks, and the patient's agreement with the expected treatment plan.

8.1.4 Last, formal psychological or psychosocial evaluation may be considered 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.

8.2 Home therapy is an important component of therapy and may include active and passive therapeutic procedures, as well as, other modalities to assist in alleviating pain, swelling, and abnormal muscle tone.

The following procedures are listed in alphabetical order.

8.3 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 a licensed acupuncturist, MD, DO, DC with appropriate training.

8.3.1 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.

8.3.2 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.

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

8.3.3.1 Time to produce effect: 3 to 6 treatments

8.3.3.2 Frequency: 1 to 3 times per week.

8.3.3.3 Maximum course duration: 14 treatments (1 course).

8.3.3.4 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. An additional course of treatment beyond 14 treatments may 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.

8.3.4 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.

8.4 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, auditorily, 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).

8.4.1 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.

8.4.2 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.

8.4.3 Time to produce effect: 3 to 4 visits.

8.4.4 Frequency: 1 to 2 times per week.

8.4.5 Maximum duration: 10 to 12 visits. Treatment beyond 12 visits must be documented

with respect to need, expectation, and ability to facilitate positive functional gains.

8.5 Injections - Therapeutic

8.5.1 Therapeutic Spinal Injections

8.5.1.1 Description: Therapeutic spinal injections may be used after initial conservative treatments have been undertaken. Therapeutic injections should be used only after imaging studies and/or diagnostic injections have established pathology. There is some evidence that the addition of steroids to a transforaminal bupivacaine injection may reduce the frequency of surgery in the first year after treatment in patients with neurologic compression and corresponding imaging findings who also are strong candidates for surgery and have completed 6 weeks of therapy without adequate benefit. There is some evidence that the benefits for the non-surgical group persisted for at least 5 years in most patients, regardless of the type of block given. An additional study provides some evidence that after 6 weeks of conservative therapy for large, herniated discs, an epidural injection may be attempted, as it does not compromise the results of a discectomy at a later date.

8.5.1.2 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.

8.5.1.3 Epidural Steroid Injection (ESI)

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

8.5.1.3.2 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.

8.5.1.3.3 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.

8.5.1.3.4 Frequency: One or more 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. Injections can be repeated if the patient has demonstrated functional gain and/or pain returns or worsens.

8.5.1.3.5 Maximum duration: 6 treatments (a treatment may include injections at 1 or 2 levels) may be done in 1 year, as per the patient's response to pain and function. Patients should be reassessed for improvement in pain (as measured by accepted pain scales) and/or evidence of functional improvement.

8.5.1.3.6 Spinal stenosis patients: Patients with radicular findings: When the patient has documented spinal stenosis, has completed 4-6 weeks of active therapy, has persistent radicular findings and difficulty with some activities. Because stenosis is not likely to change anatomically, unlike herniated discs which recede overtime, and due to the success rate of surgery for this condition in most cases, early surgical consultation is encouraged whenever the patient remains symptomatic after conservative therapy. If the patient does not which to have a surgical intervention 2 additional injections may be provided if the original diagnostic intervention was successful per guideline standards.

8.5.1.3.7 Patients with claudication: The patient has documented spinal stenosis, has completed 4 to 6 weeks of active therapy, has persistent claudication symptoms and difficulty with some activities, thus meeting criteria for surgical

intervention. The patient may have 1 injection for diagnostic purposes. Patients who have any objective neurologic findings should proceed as the above patient with radicular findings for whom an early surgical consultation is recommended. There is some evidence that translaminar steroid injections do not increase walking tolerance for those with spinal stenosis compared to local anesthetic. Those who have mild claudication, or moderate or severe claudication and who do not desire surgery, may continue to receive up to 2 additional injections if the original diagnostic intervention was successful per guidelines standards.

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

8.5.1.3.7.2 It is obligatory that sufficient data be accumulated by the examiner performing this procedure such that the value of the procedure is evident to other reviewers. This entails documentation of patient response regarding the degree and type of response to specific symptoms.

8.5.1.4 Zygapophyseal (Facet) Injection

8.5.1.4.1 Description: A generally accepted intra-articular or pericapsular injection of local anesthetic and corticosteroid.

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

8.5.1.4.3 Indications: Patients with pain suspected to be facet mediated in origin. In these patients, facet injections may be occasionally useful in facilitating rehabilitation

8.5.1.4.4 Facet injections may be repeated if they result in increased documented functional benefit for at least 4 to 6 weeks and/or at least an 50% initial improvement in pain scales as measured by accepted pain scales (such as VAS).

8.5.1.4.5 Maximum duration: 4 per level per year. Maximum 3 levels

8.5.1.5 Sacroiliac Joint Injection

8.5.1.5.1 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.

8.5.1.5.2 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. These injections may be repeated if they result in increased documented functional benefit for at least 6 weeks and/or at least an 50% initial improvement in pain scales as measured by accepted pain scales (such as VAS).

8.5.1.5.3 Maximum duration: 4 injections per year.

8.5.1.6 Intradiscal Therapy. Intradiscal 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.

8.5.2 Radio Frequency Medial Branch Neurotomy/facet rhizotomy or Basivertebral Neurotomy

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

8.5.2.1.1 There is good evidence to support Radio Frequency Medial Branch Neurotomy or Basivertebral Neurotomy in the lumbar spine for carefully selected patients who had 50% relief with medical branch controlled blinded blocks or have Type 1 or 2 Modic changes of the vertebral endplates Facet RF neurotomy will have improved pain relief over 6 months and decreased impairment compared to those who had sham procedures.

8.5.2.1.2 For Medial Branch blocks, generally, pain relief lasts 7-9 months and repeat radiofrequency neurotomy can be successful and last longer. For Basivertebral pain, a pain reduction of 65% has been shown to last up to 5 years. 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. Permanent images should be recorded to verify placement of the device.

8.5.2.2 Indications: Those patients with significant, facetogenic or vertebrogenic pain that are considered for rhizotomy may have the following symptoms:

8.5.2.2.1 Physical exam findings consistent with facet or vertebrogenic origin pain.

8.5.2.2.2 Positive response to controlled medial branch blocks or Type 1 or 2 Modic changes on MRI.

8.5.2.2.3 At least 3 months of pain, unresponsive to 6-8 weeks of conservative therapies, including manual therapy.

8.5.2.3 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.

A separate comparative block on a different date may be performed to confirm the level of involvement. A comparative block uses anesthetics with varying lengths of activity.

8.5.2.4 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.

8.5.2.5 Requirements for Repeat Radiofrequency Medial Branch Neurotomy (or additional-level RF~~)~~: Neurotomy. In some cases, pain may recur. Successful RF Neurotomy usually provides from 6 to 18 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.

8.5.3 Sacro-iliac (SI) Joint Radiofrequency Denervation – Sacro-iliac (SI) Joint. This procedure requires neurotomy of multiple nerves, L5 dorsal ramus, and lat- eral branches of S1-S3 under C-arm fluoroscopy. There is good evidence that cooled RF neurotomy performed in a highly selected population results in better pain relief and functional gains than a sham procedure. The benefits persisted for 9 months. Approximately half of the patients had benefits initially and approxi-

mately half of those reported the pain was completely relieved.

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

8.5.3.2 Indications: The following 3 requirements must be fulfilled:

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

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

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

8.5.3.3 Two fluoroscopically guided comparative blocks of the appropriate branches with different anesthetics, 50% relief of pain for the appropriate time periods, and functional improvement must be documented to meet standards for control blocks.

8.5.3.4 Requirements for Repeat Radiofrequency SI Joint Neurotomy: In some cases, pain may recur. Successful RF Neurotomy usually provides from 6 to 18 months of relief. Repeat neurotomy should only be performed if the initial procedure resulted in improvement function for 6 months.

8.6 Injections – Other

The following are in alphabetical order:

8.6.1 Botulinum Toxin Injections

8.6.1.1 Description: Used to temporarily weaken or paralyze muscles.

These injections may reduce muscle pain in conditions associated with spasticity or dystonia. Neutralizing antibodies develop in at least 4% of patients treated with botulinum toxin type A, rendering it ineffective. Several antigenic types of botulinum toxin have been described. Botulinum toxin type B, first approved by the Food and Drug Administration (FDA) in 2001, is similar pharmacologically to botulinum toxin type A. It appears to be effective in patients who have become resistant to the type A toxin. The immune responses to botulinum toxins type A and B are not cross-reactive, allowing type B toxin to be used when type A action is blocked by antibody. Experimental work with healthy human volunteers suggests that muscle paralysis from type B toxin is not as complete or as long lasting as that resulting from type A.

8.6.1.2 The duration of treatment effect of botulinum toxin type B for lumbar dystonia has been estimated to be 12 to 16 weeks. Electromyography (EMG) needle guidance may permit more precise delivery of botulinum toxin to

the target area. There is a lack of adequate evidence supporting the use of theseinjections to lumbar musculature for the relief of isolated low back pain. There is insufficient evidence to support its use for longer-term pain relief of other myofascial trigger points and it is likely to cause muscle weakness or atrophy if used repeatedly. Examples of such consequences include subacromial impingement, as the stabilizers of the shoulder are weakened by repeated injections of trigger points in the upper trapezii. Therefore, it is not recommended for use for low back pain or other myofascial trigger points.

8.6.2 Epiduroscopy and Epidural Lysis of Adhesions is an investigation 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 impeded 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 fine 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.

8.6.3 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.

8.6.4 Trigger Point Injections and Dry Needling Treatment

8.6.4.1 Description: Trigger point injections and dry needling 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. Injection efficacy may 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. 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.

8.6.4.2 Indications: Trigger point injections and dry needling may be used to relieve myofascial pain and facilitate active therapy and stretching of the affected areas. They are to be used as an adjunctive treatment in combination with other treatment modalities such as functional restoration programs. Trigger point injections and dry needling should be utilized primarily for the purpose of facilitating functional progress. Patients should continue in 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 and dry needling are indicated in those patients where well circumscribed trigger points have been consistently observed. Generally, these injections and dry needling 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 or dry needling may be occasionally effective when utilized in the patient with immediate, acute onset of low back pain.

8.6.4.3 Frequency: Weekly. Suggest no more than 4 injection sites per session per week to avoid significant post-injection soreness.

8.6.4.4 Maximum duration: 8 weeks. Occasional patients may require 2 to 4 repetitions over a 1 to 2 year period.

8.6.5 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 risk of elevated pressures which may impede blood flow and venous return, possibly causing ischemia of the cauda equina and retinal hemorrhage.

8.6.5.1 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.

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

8.7 Medications

8.7.1 Medications used 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. 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 medication lists below do not provide complete information on side effects or drug interactions. Providers should seek information for other sources for details.

8.7.1.1 The use of generic medications is encouraged. The list below is not all inclusive. It is accepted that medications not on this list may be appropriate for use in the care of the injured worker.

8.7.1.2 The following are listed in alphabetical order:

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

8.7.2.1 Optimum duration: 7 to 10 days.

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

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

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

8.7.5 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 all central nervous system (CNS) side effects ~~of~~ including drowsiness or dizziness and the fact that benzodiazepines may be habit-forming. Carisoprodol should not be used as its active metabolite, meprobamate is commonly abused. Chronic use of benzodiazepines or any muscle relaxant is not recommended due to their habit-forming potential, seizure risk following abrupt withdrawal, and documented contribution to deaths of patients on opioids due to respiratory depression. A number of muscle relaxants interact with other medications.

8.7.5.1 Optimum duration: 1 week.

8.7.5.2 Maximum duration: 2 weeks (or longer if used only at night).

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

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

8.7.6.1 Non-Selective Non-Steroidal Anti-Inflammatory Drugs. Includes NSAIDs and acetylsalicylic acid (aspirin). Serious GI toxicity, such as bleeding, perforation, and ulceration can occur at any time, with or without warning symptoms, in patients treated with traditional NSAIDs. Physicians should inform patients about the signs and/or symptoms of serious GI toxicity and what steps to take if they occur. Anaphylactoid

reactions may occur in patients taking NSAIDs. NSAIDs may interfere with platelet function. Fluid retention and edema have been observed in some patients taking.

8.7.6.2 Selective Cyclo-oxygenase-2 (COX-2) Inhibitors

8.7.6.2.1 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.

8.7.6.2.2 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.

8.7.7 Opioids. Opioids should be reserved for the treatment of acute severe low back pain. There are circumstances where prolonged use of opioids is justified based on diagnosis and severity of functional deficits, and in these cases, it should be documented and justified. In mild to moderate cases of low back pain, opioid medication should be used cautiously on a case-by-case basis. Adverse effects include respiratory depression, the development of physical and psychological dependence, and impaired alertness. Opioid medications should e prescribed with strict time, quantity, and duration guidelines, and with definite cessation parameters. Pain is subjective in nature and should be evaluated using a scale to rate effectiveness of the opioid prescribed. Any use beyond the maximum should be documented and justified based on the diagnosis and/or invasive procedures.

8.7.8 Oral Steroids**.** Oral Steroids have limited use but are accepted in cases requiring potent anti-inflammatory drug effect.

8.7.9 Psychotropic/Anti-anxiety/Hypnotic Agents. These 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 with difficulty sleeping but have more frequent side effects.

8.7.9.1 Anti-anxiety medications should generally be limited to short-term use. Accompanying sleep disorders are best treated with sedating anti-depressants prior to bedtime. Frequently, 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.

8.7.9.2 Optimum duration: 1 to 6 months.

8.7.9.3 Maximum duration: 6 to 12 months, with monitoring.

8.7.10 Tramadol. This medicine is useful in relief of low back pain and has been shown to provide pain relief equivalent to that of commonly prescribed NSAIDs. Tramadol is an atypical opioid with norepinephrine and serotonin reuptake inhibition. 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, some muscle relaxants, and tricyclic antidepressants. Because it inhibits the reuptake of norepinephrine and serotonin, use with other agents that increase norepinephrine and/or serotonin (e.g., SNRIs, mirtazapine, TCAs, SSRIs) can result in serotonin syndrome. This medication has physically addictive properties, and withdrawal may follow abrupt discontinuation; thus, it is not generally recommended for those with prior opioid addiction.

8.8 Occupational Rehabilitation Programs

8.8.1 Non-Interdisciplinary. These generally accepted programs are work-related,

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

8.8.1.1 Spinal Cord Programs

8.8.1.1.1 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.

8.8.1.1.2 Time frame 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.

8.9 Orthotics

8.9.1 Foot Orthoses and Inserts. Those 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.

8.9.2 Lumbar Support Devices. 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.

8.9.3 Lumbar Corsets and Black Belts. 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.

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

8.10 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.

8.10.1 Time to produce effect: Varies with individual patient.

8.10.2 Frequency: Should occur at every visit.

8.11 Personality/Psychological/Psychosocial Intervention

8.11.1 Psychosocial treatment is a well-established therapeutic and diagnostic intervention with selected use in acute chronic pain problems and more widespread use in sub-acute and chronic pain populations. Psychosocial treatment is recommended as an important component in the total management of a patient with chronic low back pain and should be implemented as soon as the problem is identified.

If a diagnosis consistent with the standards of the American Psychiatric Association's Diagnostic and Statistical Manual of Mental Disorders (DSM) has been determined, the patient should be evaluated for the potential need for psychiatric medications. Use of any medication

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

8.11.2 Psychosocial interventions including psychotherapeutic treatments for mental health conditions, as well as behavioral medicine treatments. These interventions may similarly be beneficial for patients without psychiatric conditions, but who may need to make major life changes in order to cope with pain or adjust to disability. Examples of these treatments include cognitive behavioral therapy (CBT), relaxation training, mindfulness training, and sleep hygiene training.

8.11.3 The screening or diagnostic workup should clarify and distinguish between pre-existing, aggravated, and/or purely causative psychological conditions. Therapeutic and diagnostic modalities include, but are not limited to, individual counseling and group therapy. Treatment can occur within an individualized model, a multi-disciplinary model, or a structured pain management program.

8.11.4 A psychologist with a PhD, PsyD, EdD credentials, a psychiatric MD/DO credentials, or a clinical social worker (CSW) with appropriate licensure for therapy may perform psychosocial treatments. Other licensed mental health providers or licensed health care providers with training in CBT or certified as CBT therapists who have experience in treating chronic pain disorders in injured workers, may also perform treatment in consultation with a PhD, PsyD, EdD or psychiatric MD/DO.

8.11.5 CBT refers to a group of psychological therapies that are sometimes referred to by more specific names, such as Rational Emotive Behavior Therapy, Rational Behavior Therapy, Rational Living Therapy, Cognitive Therapy, and Dialectic Behavior Therapy. Variations of CBT methods can be used to treat a variety of conditions, including chronic pain, depression, anxiety, phobias, and post-traumatic stress disorder (PTSD). For patients with multiple diagnoses, more than one type of CBT might be needed. The CBT used in research studies is often “manualized CBT,” meaning that the treatment follows a specific protocol in a manual. In clinical settings, CBT may involve the use of standardized materials, but it is also commonly adopted by a psychologist or psychiatrist to the patient’s unique circumstances. If the CBT is being performed by a non-mental health professional, a manual approach would be strongly recommended. CBT must be distinguished from neuropsychological therapies used to teach compensatory strategies for brain injured patients, which are also called “cognitive therapy.”

8.11.5.1 If should be noted that most clinical trials on CBT exclude subjects who have significant psychiatric diagnoses. Consequently, the selection of patients for CBT should include the following considerations. CBT is instructive and structured, using an education model with homework to teach inductive rational thinking. Because of this educational model, a certain level of literacy is assumed for most CBT protocols. Patients who lack the cognitive and educational abilities required by a CBT protocol are unlikely to be successful. Further, given the highly structured nature of CBT, it is more effective when a patient’s circumstances are relatively stable. For example, if a patient is about to be evicted, is actively suicidal, or is coming to sessions intoxicated, these matters will generally preempt CBT treatment for pain, and require other types of psychotherapeutic response. Conversely, literate patients whose circumstances are relatively stable, but who catastrophize or cope poorly with pain or disability are often good candidates for CBT for pain. Similarly, literate patients whose circumstances are relatively stable, but who exhibit unfounded medical phobias, are often good candidates for CBT for anxiety. There is good evidence that cognitive intervention reduces low back disability in the short term and in the long term. In one of the studies the therapy consisted of 6, 2-hour sessions given weekly to workers who had been sick-listed for 8-12 weeks. Comparison groups included those who received routine care. There is good evidence that psychological interventions, especially CBT, are superior to no psychological intervention for chronic low back pain, and that self-regulatory interventions, such as biofeedback and relaxation training, may be equally effective. There is good evidence that 6 group therapy sessions lasting 1 ½ hours each focused on CBT skills improved function and alleviated pain in uncomplicated sub-acute and chronic low back pain patients. There is some evidence that CBT provided in 7, 2-hour small group sessions can reduce the severity of insomnia in chronic pain patients. A Cochrane meta-analysis grouped very heterogenous behavioral interventions and conduced that there was good evidence that CBT may reduce pain and disability, but the

effect size was uncertain. In total, the evidence clearly supports CBT, and it should be offered to all chronic pain patients who do not have other serious issues, as discussed above.

8.11.5.2 CBT is often combined with active therapy in an interdisciplinary program, whether formal or informal. It must be coordinated with a psychologist or psychiatrist. CBT can be done in a small group or individually, and the usual number of treatments varies between 8 and 16 sessions.

8.11.5.3 Before CBT is done, the patient must have a full psychological evaluation. The CBT program must be done under the supervision of a PhD, PsyD, EdD, or psychiatric MD/DO.

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

For all psychological/psychiatric interventions, an assessment and treatment plan with measurable behavioral goals, time frames, and specific interventions planned, must be provided to the treating physician prior to initiating treatment. A status report must be provided to the authorized treating physician every 2 weeks during initial more treatment and monthly thereafter. The report should provide documentation of progress toward functional recovery and a discussion of the psychosocial issues affecting the patient's ability to participate in treatment. The report should also address pertinent issues such as pre-existing, aggravated, and/or causative issues, as well as realistic functional prognosis.

8.11.7 Cognitive Behavioral therapy (CBT) or Similar Treatment

8.11.7.1 Time to produce effect: 6 to 8 1-2-hour sessions, group or individual (1-hour individual or 2-hour group).

8.11.7.2 Maximum duration: 16 sessions.

NOTE: Before CBT is done, the patient must have a full psychological evaluation. The CBT program must be done under the supervision of a PhD, PsyD, EdD, or Psychiatric MD/DO credentials, or a clinical social worker (CSW) with appropriate licensure for therapy.

8.11.8 Other Psychological/Psychiatric Interventions

8.11.8.1 Time to produce effect: 6 to 8 weeks.

8.11.8.2 Frequency: 1 to 2 times weekly for the first 2 weeks (excluding hospitalization, if required), decreasing to 1 time per week for the second month. Thereafter, 2 to 4 times monthly with the exception of exacerbations, which may require increased frequency of visits. Not to include visits for medication management.

8.11.8.3 Optimum duration: 2 to 6 months.

8.11.8.4 Maximum duration: 6 months. Not to include visits for medication management. For select patients, longer supervised psychological/psychiatric treatment may be required, especially if there are ongoing medical procedures or complications. If counseling beyond 6 months is indicated, the management of psychosocial risks or functional progress must be documented. Treatment plan/progress must show severity.

8.12 Restriction of Activities

8.12.1 Continuation of normal daily activities is the recommendation for acute and chronic low back pain without neurologic symptoms. Prolonged immobility results in a wide range of deleterious effects, such as a reduction in aerobic capacity and conditioning, loss of muscle strength and flexibility, increased segmental stiffness, promotion of bone demineralization, impaired disc nutrition, and the facilitation of the illness role.

8.12.2 Immobility may range from bed rest to the continued use of orthotics, such as lumbar support braces. While these interventions may occasionally have been ordered in the acute phase, the provider should be aware of their impact on the patient's ability to adequately comply with and successfully complete rehabilitation. There is strong evidence against the use of bed rest in acute low back cases without neurologic symptoms. Activity should be increased based on the improvement of core strengthening.

8.12.3 Patients should be educated regarding the detrimental effects of immobility versus the efficacious use of limited rest periods. Adequate rest allows the patient to comply with active treatment and benefit from the rehabilitation program. In addition, complete work cessation should be avoided, if possible since it often further aggravates the pain presentation and promotes disability. Modified return-to-work is almost always more efficacious and rarely contraindicated in the vast majority of injured workers with low back pain.

8.13 Therapy – Passive

8.13.1 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 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.

8.13.2 Generally, passive interventions are viewed as a means to facilitate progress in an active rehabilitation program with concomitant attainment of objective functional gains. All rehabilitation programs must incorporate “Active Interventions” no later than 12 visits or 3 weeks after the onset of treatment. Reimbursement for passive modalities only after the first

12 visits or 3 weeks of treatment without clear evidence of Active Interventions will require supportive documentation.

8.13.3 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 following passive therapies are listed in alphabetical order:

8.13.4 Electrical Stimulation (Unattended and Attended) is an accepted treatment. Once applied, unattended electrical stimulation requires minimal on-site supervision by the 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.

8.13.4.1 Time to produce effect: 2 to 4 treatments.

8.13.4.2 Maximum duration: 14 ~~visits~~ visits.

8.13.5 Iontophoresis is an accepted treatment which consists of the transfer of medication, includingsteroidal 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.

8.13.5.1 Time to produce effect: 1 to 4 treatments.

8.13.5.2 Frequency: 3 times per week with at least 48 hours between treatments.

8.13.5.3 Maximum duration: 8 visits per body region.

8.13.6 Manipulation is a 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.

8.13.6.1 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.), 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.

8.13.6.2 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. 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 arthritis, aortic aneurysm, and signs of progressive neurologic deficits.

8.13.6.3 Time to produce effect for all types of manipulative treatment: 1 to 6 treatments.

8.13.6.4 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.

8.13.6.5 Maximum duration: 36 visits. 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 6 months.
The combination of 97140 plus either CMT or OMT code is equal to one visit when performed on the same day. Any combination of manual therapeutic intervention exceeding 36 visits (not units) need to go to UR.

8.13.6.6 Mobilization (Joint)/Manipulation

Mobilization is passive movement involving oscillatory motions to the involved joints. The passive mobility is performed in a graded manner (I, II, III, IV, or V), which depicts the speed of the maneuver. It may include skilled manual joint tissue stretching. Indications include the need to improve joint play, improve intracapsular arthrokinematics, or reduce pain associated with tissue impingement.

8.13.6.6.1 Time to produce effect: 4 to 6 treatments.

8.13.6.6.2 Frequency: 2 to 3 times per week.

8.13.6.6.3 Maximum duration: 36 visits (CPT codes 97124 and 97140 cannot exceed 36 visits in combination).

8.13.7 Massage – Manual or Mechanical. Massage is manipulation of soft tissue with broad ranging relaxation and circulatory benefits. This may include 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.

8.13.7.1 Time to produce effect: Immediate.

8.13.7.2 Frequency: 1 to 3 times per week.

8.13.7.3 Maximum duration: 12 visits (CPT codes 97124 and 97140 cannot exceed 36 visits in combination).

8.13.8 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. 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 arthritis, aortic aneurysm, and signs of progressive neurologic deficits.

8.13.8.1 Time to produce effect for all types of manipulative treatment: 1 to 6 treatments.

8.13.8.2 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.

8.13.8.3 Maximum duration: 36 visits. 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 6 months. (CPT codes 97124 and 97140 cannot exceed 36 visits in combination).

8.13.8.4 Re-evaluate Treatment Every 10 to 12 Treatments. If a given treatment or modality is not producing positive results within 10 to 12 treatments, the treatment may be either modified or discontinued. Reconsideration of diagnosis should also occur in the event of poor response to a seemingly rational intervention.

8.13.9 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.

8.13.9.1 Maximum duration: 36 visits (CPT codes 97124 and 97140 cannot exceed 36 visits in combination).

8.13.9.2 Re-Evaluate Treatment Every 10 to 12 Treatments. If a given treatment or modality is not producing positive results within 10 to 12 treatments, the treatment may be either modified or discontinued. Reconsideration of diagnosis should also occur in the event of poor response to a seemingly rational intervention.

8.13.10 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. It is an accepted modality as an adjunct to acupuncture or situation where other forms of contact superficial heat are contraindicated.

8.13.11 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.

8.13.11.1 Time to produce effect: Immediate.

8.13.11.2 Frequency: 2 to 5 times per week.

8.13.11.3 Maximum duration: 12 visits with a maximum of 1 unit per day.

8.13.12 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.

8.13.13 Traction – Mechanical. 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. Motorized traction/decompression devices are included (i.e. VAX-D, DRX9000,etc.) A home lumbar traction unit can be purchased if therapy proves effective.

8.13.13.1 Time to produce effect: 1 to 3 sessions up to 30 minutes. If response is negative after 3 treatments, discontinue this modality.

8.13.13.2 Frequency: 2 to 3 times per week. A home lumbar traction unit can be purchased if therapy proves effective.

8.13.13.3 Maximum duration: 24 visits.

8.13.14 Transcutaneous Electrical Nerve Stimulation (TENS) is a generally accepted treatment. TENS should include at least ~~one~~ 1 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 should be documented prior to the purchase of a home unit.

8.13.14.1 Time to produce effect: Immediate.

8.13.14.2 Frequency: Variable.

8.13.15 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. Phonophoresis is not recommended for low back pain.

8.13.15.1 Time to produce effect: 6 to 15 treatments.

8.13.15.2 Frequency: 3 times per week.

8.13.15.3 Maximum duration: 18 visits.

8.13.16 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. This is not recommended for low back pain.

8.14 Therapy – Active

8.14.1 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.

8.14.2 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 following active therapies are listed in alphabetical order:

8.14.3 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.

8.14.3.1 Time to produce effect: 4 to 5 ~~treatments~~ treatments.

8.14.3.2 Maximum duration: 10 ~~visits~~ visits.

8.14.4 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:

8.14.4.1 Cannot tolerate active land-based or full-weight bearing therapeutic procedures;

8.14.4.2 Require increased support in the presence of proprioceptive deficit;

8.14.4.3 Are at risk of compression fracture due to decreased bone density;

8.14.4.4 Have symptoms that are exacerbated in a dry environment;

8.14.4.5 Would have a higher probability of meeting active therapeutic goals than in a land-based 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.

8.14.4.6 Time to produce effect: 4 to 5 treatments.

8.14.4.7 Frequency: 3 to 5 times per week.

8.14.4.8 Maximum duration: 20 visits.

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

8.14.5 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.

8.14.5.1 Time to produce effect: 4 to 5 treatments.

8.14.5.2 Frequency: 3 to 5 times per week.

8.14.5.3 Maximum duration: 24 visits.

Total number of visits 97110 and 97530 should not exceed 36 visits without pre-authorization.

8.14.6 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 impaired muscle function to radiculopathy. (Foot drop)

8.14.6.1 Time to produce effect: 2 to 6 treatments.

8.14.6.2 Frequency: 3 times per week.

8.14.6.3 Maximum duration: 14 visits inclusive of electrical muscle stimulation codes if beneficial provide with home unit.

8.14.7 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.

8.14.7.1 Time to produce effect: 2 to 6 treatments.

8.14.7.2 Frequency: 3-5 times per week.

8.14.7.3 Maximum duration: 30 visits.

8.14.8 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.

8.14.8.1 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).

8.14.8.2 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.

8.14.8.3 Time to produce effect: 2 to 6 treatments.

8.14.8.4 Frequency: 3 to 5 times per week.

8.14.8.5 Maximum duration: 30 visits.

Total number of visits of 97110 and 97530 may not exceed 36 visits without pre-authorization.

9.0 Therapeutic Procedures - Operative

9.1 General

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

9.1.2 Operative treatment is indicated when the natural history of surgically treated lesions is better than the natural history of 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, an accurate diagnosis and timely decision making for operative intervention ~~is~~ are critical. Thorough neurologic exams should be performed periodically to assure timely treatment; to avoid de-conditioning and increased

disability; and to treat emergent pathology or neurologically compromising conditions which may require early surgery.

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

9.1.4 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 therapy and manual treatment (mere passage of time with poorly guided treatment is not considered an active treatment program). In cases of myelopathy and some cases of severe nerve root compression, earlier intervention is indicated; or Frequent recurrences of symptoms cause serious functional limitations even if a non-operative active treatment program provides significant improvement of symptoms, and restoration of function on each recurrence; or The patient and treatment physician have identified functional operative goals and the likelihood of achieving improved ability to perform activities of daily living or work activities. The patient should agree to comply with the pre- and post-operative treatment plan including home exercise. The provider should be especially careful to make sure the patient understands the amount of postoperative treatment required and the length of partial- and full-disability expected postoperatively. The patient should have committed to the recommended post-operative treatment plan and fully completed the recommended active, manual, and pre-operative treatment plans.

9.1.5 There are some clinical scenarios which necessitate surgical interventions. Surgical workup and implementation of decompression of patients with herniated nucleus pulposus and radiculopathy should occur within 6 to 12 weeks, at the latest, after injury within the above stated contingencies. Small herniations and most protrusions are often not pain generators, however small foraminal disc herniations are likely to compress the nerve root and may require surgical removal.

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

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

9.1.6.2 Physical exam findings of abnormal reflexes, motor weakness or radicular sensation deficits;

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

9.1.7 Treatment of myelopathy may occur earlier. Surgical procedures should be directed toward neurological findings which correlate with MRI imaging. For the unusual patients with refractory lumbar pain in whom fusion is being considered, it is strongly recommended that a decisive commitment to surgical or non-surgical interventions occur within 5 months following injury.

9.1.8 Spinal decompression surgeries and fusions have a re-operation rate 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 standing, walking, strength, endurance, functional lumbar range of motion, and/or vocational status. While timely surgical decision-making is critical to avoid de-conditioning and increased disability, a time limited trial of reconditioning may be tried prior to re-operation. Re-operation has a high rate of complications and failure and may lead to disproportionately increased disability.

9.1.9 Every post-operative patient should be involved in an active treatment program after clearance by the surgeon. Interdisciplinary interventions should be strongly considered post-operatively in any patient not making functional progress within expected time frames, if available.

9.1.10 Informed decision making should be documented for all invasive procedures. This must include a thorough discussion of the pros and cons of the procedure and the possible complications as well as the natural history of the identified diagnosis. Since most patients with the most common conditions will improve significantly over time, without invasive interventions, patients must be able to make well-informed decisions regarding their

treatment.

9.1.11 Return to work restrictions should be specific. Full activity is generally achieved between 3 months to 1 year, depending on the procedure, the type of duties performed, and healing of the individual. Patient should be informed of expected time off work.

9.2 Discectomy and Nerve Root Decompression

9.2.1 Description: To enter into and partially remove the disc and/or Decompress Nerve Root. May be an open procedure or minimally invasive, and usually involves partial laminectomy.

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

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

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

9.2.4 Operative Treatment: Partial discectomy and root decompression.

9.2.5 Post-Operative Therapy: An individualized rehabilitation program based upon communication between the surgeon and the therapist. In all cases, communication between the physician and therapist is important to the timing of exercise progressions. Post-operative active treatment will frequently require a repeat of the therapy sessions previously ordered. The implementation of a gentle aerobic reconditioning program (e.g., walking) and back education within the first post-operative week is appropriate in uncomplicated post-surgical cases. Some patients may benefit from several occupational therapy visits to improvement performance of ADLs. Participation in an active therapy program which includes restoration of ROM, core stabilization, strengthening, and endurance is often recommended to be initiated 3 to 12 weeks post-operative. The goals of the therapy program should include instruction in a long-term home-based exercise program.

9.3 Percutaneous Discectomy

9.3.1 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.

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

9.3.3 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.

9.4 Laminotomy/Laminectomy/Foramenotomy/Facetectomy

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

9.4.2 Surgical Indications: May include the following:

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

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

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

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

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

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

9.4.4 Post-Operative Therapy: An individualized rehabilitation program based upon communication between the surgeon and the therapist. In all cases, communication between the physician and therapist is important to the timing of exercise progressions. Post-operative active treatment will frequently require a repeat of the therapy sessions previously ordered. The implementation of a gentle aerobic reconditioning program (e.g., walking) and back education within the first post-operative week is appropriate in uncomplicated post-surgical cases. Some patients may benefit from several occupational therapy visits to improve performance of ADLs. Participation in an active therapy program which includes restoration of ROM, core stabilization, strengthening, and endurance is often recommended to be initiated 3 to 12 weeks post-operatively. The goals of the therapy program should include instruction in a long-term home-based exercise program. Medium or heavy lifting should not be begun before 10 to 12 weeks in most cases.

9.5 Spinal Fusion

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

9.5.2 Surgical Indications: A timely decision-making process is recommended when considering patients for possible fusion. The treatment for some patients with lumbar fractures may be immediate fusion. For chronic low back problems, fusion should not be considered within the first 4 months of symptoms, except for fracture, dislocation, recurrent herniation, or instability for some patients with functional loss due to stenosis or instability.

There is good evidence that decompression and fusion, with or without instrumentation, of lumbar stenosis with degenerative spondylolisthesis leads to better 2-year outcomes

for patients whose symptoms are severe. Physicians should consider this when advocating for surgical procedures in this population. To assure better outcomes fusions should only be performed on those who meet the indications below.

9.5.3 Indications for spinal fusion may include:

9.5.3.1 Neural arch defect: Spondylolytic spondylolisthesis, congenital unilateral neural arch hypoplasia.

9.5.3.2 Segmental Instability: Excessive motion, as in degenerative spondylolisthesis, surgically induced segmental instability.

9.5.3.3 Primary Mechanical Back Pain/Functional Spinal Unit ~~F~~Failure: Multiple pain generators objectively involving two or more of the following: internal disc disruption (poor success rate if more than two disc involved), painful motion segment, as in annular tears, disc resorption, facet syndrome, ligamentous tear, and/or degenerative disc disease.

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

9.5.3.5 History of multiple recurrent herniated discs.

9.5.3.6 Other diagnoses: Infection, tumor, or deformity of the

lumbosacral spine that cause intractable pain, neurological deficit, and/or functional disability.

9.5.3.7 Spine fusion surgery may result in Adjacent Segmental Degeneration.

9.5.4 Pre-operative Surgical Indications: Required pre-operative clinical surgical indications for spinal fusion may include all of the following:

9.5.4.1 All conservative care interventions ae completed; and the patient remains symptomatic.

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

9.5.4.3 Planned fusion to exceed 2 levels requires confirmatory second opinion.

9.5.4.4 For any potential fusion surgery, it is recommended that the injured worker be encouraged to refrain from smoking for at least 6 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.

9.5.5 Post-operative Therapy: An individualized rehabilitation program should be based upon communication between the surgeon and the therapist. In all cases, communication between the physician and therapist is important to the timing of exercise progressions. Post-operative active treatment, which patients should have had prior to surgery, will frequently require a repeat of the visits 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. If it is performed, care should be taken not to overly mobilize the section above and below the fusion at that time. ~~the~~ The goals of the therapy program should include instruction in a long-term home-based exercise program. The non-surgical physical therapy guidelines listed above do not apply to post-operative rehabilitation and work conditioning.

9.6 Sacroiliac Joint Fusion

9.6.1 Description: Use of bone grafts, sometimes combined with metal devices, to produce a rigid connection between 2 or more adjacent vertebrae providing symptomatic stability as a part of major pelvic ring disruption.

9.6.2 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.

9.7 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.

9.8 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. Due to lack of evidence indicating benefit from this procedure, it is not recommended.

9.9 Interspinal Spacers

9.9.1 Description: Multiple interspinous spacer devices (IFDs) have been utilized.

to treat older patients (age 50 and over) with lumbar spinal stenosis (LSS) and intermittent neurogenic claudication (INC) Interspinous process decompression theoretically relieves

narrowing of the spinal canal and neural foramen in extension, thereby reducing the symptoms of INC, secondary to lumbar spinal stenosis (LSS).

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

Patients who meet the following may be considered:

9.9.2.1 All pain generators are adequately defined and treated;

9.9.2.2 All physical medicine and manual therapy interventions are completed over 6 months;

9.9.2.3 Impaired physical function correlated with physical findings;

9.9.2.4 CT or MRI that demonstrates stenosis;

9.9.2.5 Spine pathology is limited to 1 or 2 levels.

9.9.3 Contraindications

9.9.3.1 Anatomy that prevents implantation due to significant lumbar instability, ankylosis, acute fracture of the spinous process or pars interarticularis.

9.9.3.2 Allergy to titanium or titanium alloy.

9.9.3.3 Significant scoliosis.

9.9.3.4 Fixed motor deficit.

9.9.3.5 Cauda equina syndrome.

9.8.3.6 Neural compression causing neurogenic bowel or bladder dysfunction.

9.9.3.7 Previous lumbar surgery.

9.9.3.8 Significant peripheral neuropathy.

9.9.3.9 Spondylolisthesis greater than 1.0 (on a scale from 1-4) at the affected level.

9.9.3.10 Sustained pathological fractures.

9.9.3.11 Severe osteoporosis of the vertebrae or hips.

9.9.3.12 Severe foraminal stenosis.

9.9.3.13 Obesity.

9.9.3.14 Active infection or systemic disease.

9.9.3.15 Paget's disease or metastasis to the vertebrae.

9.9.3.16 Steroid use for more than 1 month within 12 months preceding surgery.

9.9.3.17 Relative contraindication: adjacent level disease.

9.9.4 Post-Procedure Therapy. A formal physical therapy program should be implemented postoperatively. Some patients may benefit from several occupational therapy visits. Rehabilitation may take as long as 6 months and include stretching during the first month, floor exercise program, and sports activities in the 5 and 6 months as tolerated. The goals of the therapy program should include instruction in a long-term home base exercise program.

9.10 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.

9.11 Artificial Lumbar Disc Replacement

9.11.1 Description: This procedure 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.

9.11.1.1 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.

9.11.1.2 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.

9.11.2 Surgical Indications

9.11.2.1 Symptomatic one-level degenerative disc disease established by objective testing (CT or MRI scan followed by positive provocation discogram, if necessary).

9.11.2.2 Symptoms unrelieved after 6 months of active non-surgical treatment, including physical medicine and manual therapy interventions.

9.11.3 Contraindications

9.11.3.1 Significant spinal deformity/scoliosis.

9.11.3.2 Symptomatic facet joint arthrosis.

9.11.3.3 Spinal instability at the pathologic or adjacent level requiring fusion.

9.11.3.4 Deficient posterior elements.

9.11.3.5 Infection.

9.11.3.6 Any contraindications to an anterior abdominal approach (including multiple prior abdominal procedures).

9.11.3.7 Previous compression or burst fracture at the surgical level.

9.11.3.8 Multiple-level degenerative disc disease (DDD).

9.11.3.9 Evidence of nerve root compression, depending on the device used.

9.11.3.10 Spinal canal stenosis.

9.11.3.11 Spondylolysis.

9.11.3.12 Spondylolisthesis greater than 3 mm.

9.11.3.13 Osteoporosis or any metabolic bone disease.

9.11.3.14 Chronic steroid use or use of other medication known to interfere with bone or soft tissue healing.

9.11.3.15 Autoimmune disorder.

9.11.3.16 Allergy to device components/materials.

9.11.3.17 Morbid obesity (e.g., body/mass index [BMI] of greater than 40, over 100 pounds overweight).

9.11.3.18 Active malignancy.

9.11.3.19 Generalized chronic pain.

9.11.4 Post-operative Therapy. An individualized rehabilitation program based upon communication between the surgeon and the therapist. In all cases, communication between the physician and therapist is important to the timing of exercise progressions. Bracing may be appropriate. A formal therapy program should be implemented post-operatively. Active treatment, which patients may have had prior to surgery, will frequently

require a repeat of the visits 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~~ 6 weeks in uncomplicated cases. The goals of the therapy program should include instruction in a long-term home-based exercise program.

9.12 Kyphoplasty

9.12.1 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. There is good evidence that kyphoplasty provides rapid improvement in function in the initial months after the fracture as compared to nonoperative treatment or analgesics alone. There is clear long-term advantage. The natural history of recovery from vertebral fractures would indicate that most patients will recover in approximately 12 weeks. There is no evidence that kyphoplasty is superior to vertebroplasty.

9.12.2 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 1 month of the fracture since the elevation of the endplates may be more readily achieved than when the procedure is delayed.

9.12.3 Surgical Indications: Kyphoplasty is an accepted treatment during the first 12 weeks for all of the following indications:

9.12.3.1 Compression fracture.

9.12.3.2 Vertebral height loss between 20% and 85%.

9.12.3.3 Patients whose pain is severe while using analgesics after the first 4 weeks and who are unable to perform activities of daily living.

Kyphoplasty is more likely to increase vertebral height if performed within 30 days of fracture occurrence.

9.12.4 Contraindications

9.12.4.1 Asymptomatic vertebral body compression fracture.

9.12.4.2 Patient improvement with medical treatment.

9.12.4.3 The presence of neurologic compromise related to fracture.

9.12.4.4 High-velocity fractures with a significant burst component.

9.12.4.5 Significant posterior vertebral body wall fracture.

9.12.4.6 Severe vertebral collapse (vertebra plana).

9.12.4.7 Infection.

9.12.4.8 Coagulopathy

9.13 Vertebroplasty

9.13.1 Description: A minimally invasive surgical procedure for the treatment of painful thoracolumbar vertebral compression factures secondary to osteoporosis or other metabolic bone disease. Traditionally a low-viscosity acrylic bone cement, polymethylmethacrylate (PMMA), is injected with high pressure into the vertebral body under fluoroscopic guidance. Other types of bone cement such as high-viscosity PMMA,

glass polymers, hydroxyapatite, and calcium phosphate have recently been made commercially available. The procedure is usually performed under intravenous sedation or light general anesthesia. A bone biopsy needle or trocar needle (11- to 13-gauge) is placed into the vertebral body and cement is injected very slowly under constant fluoroscopic guidance to minimize cement leakage. The goal of the procedure is to stabilize the spine and to relieve pain.

9.13.1.1 The procedure is not primarily intended to correct spinal deformity. Vertebral body heigh correction measurements are inconsistent between studies and, as such, are not comparable. The 2 long-term studies examining lasting restoration of vertebral body height or kyphotic angle found conflicting results.

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

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

9.13.2.1 Have been radiographically confirmed;

9.13.2.2 Have been localized clinically to the level of the vertebral fracture;

9.13.2.3 Are unable to perform activities of daily living;

9.13.2.4 Have failed to respond to at least 4 weeks of conservative management;

9.13.2.5 Are between 4 and 12 weeks since pain onset;

9.13.2.6 Are sufficiently healthy to undergo surgery if necessary for decompression;

9.13.2.7 Have a vertebral height loss between 15% and 85%; and

9.13.2.8 Have an intact posterior wall.

9.13.3 Contraindications are any of the following:

9.13.3.1 Asymptomatic vertebral body compression fracture;

9.13.3.2 Patient improvement with medical treatment;

9.13.3.3 The presence of neurologic compromise related to the fracture;

9.13.3.4 High velocity fractures with a significant burst component;

9.13.3.5 Posterior vertebral body wall fracture;

9.13.3.6 Severe vertebral collapse (vertebra plana);

9.13.3.7 Spinal Canal Stenosis;

9.13.3.8 Allergy to bone cement or opacification agents;

9.13.3.9 Active or incompletely treated infection;

9.13.3.10 Uncorrectable Coagulopathy.

9.14 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.

9.15 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.

9.16 Epiduroscopy and Epidural Lysis of Adhesions (Refer to Injections-Therapeutic).

9.17 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 is frequently 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.

10.0 General Guidelines

10.1 Global Reimbursement

The reimbursement allowances for surgical procedures are based on a global reimbursement concept that covers performing the basic service and the normal range of care required after surgery. Global reimbursement includes:

10.1.1 The operation per se.

10.1.2 Local infiltration, metacarpal/metatarsal/digital block or topical anesthesia.

10.1.3 Subsequent to the decision and/or authorization for surgery, one related E/M encounter on the date immediately prior to or on the date of the procedure (including history and physical) but does not include the initial consultation.

10.1.4 Immediate postoperative care, including dictating operative notes, talking with the family and other physicians.

10.1.5 Writing orders.

10.1.6 Evaluating the patient in the post anesthesia recovery area.

10.1.7 Normal, uncomplicated follow-up care for the time periods indicated in the follow-up days (FUD) column to the right of each procedure code. The number in that column establishes the days during which no additional reimbursement is allowed for the usual care provided following surgery, absent complications or unusual circumstances.

10.1.8 The maximum reimbursement allowances cover all normal postoperative care, including the removal of sutures by the surgeon or associate. Follow-up days are specified by procedure.

Follow-up days listed are for 0, 10, or 90 days and are listed in the Fee Schedule as 000, 010, or 090.

10.2 Implants

Bone morphogenetic protein is an FDA approved biologic fusion and fracture healing aid. Its use in spine and fracture surgery represents the standard of care in our community, and in both on-label and off-label applications is accepted and to be reimbursed to the facility providing the implant, at rates consistent with implant payment rates determined under the respective ASC and hospital reimbursement guidelines

10.3 Surgical Assistant

10.3.1 Physician Surgical Assistant. For the purpose of reimbursement, a physician who assists at surgery is reimbursed as a surgical assistant. Assistant surgeons should use modifier 80 and are allowed 20% of the maximum reimbursement allowance (MRA) for the procedure(s).

10.3.2 Registered Nurse Surgical Assistant or Physician Assistant

10.3.2.1 A physician assistant, or registered nurses who have completed an approved first assistant training course, may be allowed a fee when assisting a surgeon in the operating room (O.R.).

10.3.2.2 The maximum reimbursement allowance for the physician assistant or the registered nurse first assistant (RNFA) is 20% of the surgeon's fee for the procedure(s) performed.

10.3.2.3 Under no circumstances will a fee be allowed for an assistant surgeon and a physician assistant or RNFA at the same surgical encounter.

10.3.2.4 Registered nurses on staff in the O.R. of a hospital, clinic, or outpatient surgery center do not qualify for reimbursement as an RNFA.

10.4 Therapeutic Procedures

Therapeutic procedures (injecting into cavities, nerve blocks, etc.) (CPT codes 20526–20610, 64400, 64450) may be billed in addition to the medical care for a new patient. (Use appropriate level of service plus injection.) In follow-up cases for additional therapeutic injections and/or aspirations, an office visit is only indicated if it is necessary to re-evaluate the patient. In this case, a minimal visit may be listed in addition to the injection.

Documentation supporting the office visit charge must be submitted with the bill to the payer. This is clarified in the treatment guidelines in a more specific manner. Trigger point injection is considered 1 procedure and reimbursed as such regardless of the number of injection sites. Two codes are available for reporting trigger point injections. Use 20552 for injection(s) of single or multiple trigger point(s) in 1 or 2 muscles or 20553 when 3 or more muscles are involved.

10.5 Intervertebral Biomechanical Device(s)

Code 22851 describes the application of an intervertebral biomechanical device to a vertebral defect or interspace. Code 22851 should be listed in conjunction with a primary procedure without the use of modifier 51. The use of 22851 is limited to 1 instance per single interspace or single vertebral defect regardless of the number of devices applied and infers additional qualifying training, experience, sizing, and/or use of special surgical appliances to insert the biomechanical device. Qualifying devices include manufactured synthetic or allograft biomechanical devices, or methyl methacrylate constructs, and are not dependent on a specific manufacturer, shape, or material of which it is constructed. Qualifying devices are machine cut to specific dimensions for precise application to an intervertebral defect. (For example, the use of code 22851 would be appropriate during a cervical arthrodesis (22554) when applying a synthetic alloy cage, a threaded bone dowel, or a machine cut hexahedron cortical, cancellous, or cortico cancellous allograft biomechanical device. Surgeons utilizing generic non-machined bony allografts or autografts are referred to code sets 20930–20931, 20936–20938 respectively.)

10.6 Spinal and Cranial Services Require Additional Surgeon

Certain spinal and cranial procedures require the services of an additional surgeon of a different specialty to gain exposure to the spine and brain. These typically are vascular, thoracic and ENT. The surgical exposure portion of these procedures will be billed, dictated and followed separately by the exposure surgeon for their portion of the procedure.

10.7 Multiple Procedure Reimbursement Rule

Multiple procedures performed during the same operative session at the same operative site are reimbursed at 100% of the allowable fee for the primary and all subsequent procedures.

Discography reimbursement is billed per the CPT guidelines, each level and is reimbursed per the Health Care Payment System fee schedule for each level.

10.8 External Spinal Stimulators Post Fusion

The following criteria are established for the medically accepted standard of care when determining applicability for the use of an external spinal stimulator. However, the medical necessity should be determined on a case-by-case basis.

10.8.1 Patient has had a previously failed spinal fusion; and/or

10.8.2 Patient is scheduled for revision or repair of pseudoarthrosis; and/or

10.8.3 The patient smokes greater than a pack of cigarettes per day and is scheduled for spinal fusion;

10.8.4 The external spinal stimulator is approved for use in primary spinal fusions, if medical co morbidities increase the likelihood of non-union;

10.8.5 The external spinal stimulator will be reimbursed by report (BR);

10.8.6 The patient is metabolically in poor health, with other medical co morbidities such as diabetes, Rheumatoid arthritis, lupus or other illnesses requiring oral steroids or cytotoxic medications;

10.8.7 Precertification is required for use of the external spinal stimulator if the planned use falls outside the above indications.

11 DE Reg. 1661 (06/01/08)

12 DE Reg. 67 (07/01/08)