

**TITLE 19 LABOR
DELAWARE ADMINISTRATIVE CODE**

**1000 DEPARTMENT OF LABOR
1300 Division of Industrial Affairs
1340 The Office of Workers' Compensation**

1342 Health Care Practice Guidelines

PART D Low Back Treatment Guidelines

1.0 Introduction

Pursuant to 19 **Del.C.** §2322C, health care practice guidelines have been adopted and recommended by the Health Care Advisory 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.

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.

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.

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.

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.

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).

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.

The Health Care Advisory 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.

TITLE 19 LABOR

DELAWARE ADMINISTRATIVE CODE

2

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 Health Care Advisory Panel.

2.0 General Guideline Principles

- 2.1 **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.
- 2.2 **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 twelve visits three weeks after the onset of treatment. Reimbursement for passive modalities only after the first twelve visits three weeks of treatment without clear evidence of Active Interventions will require supportive documentation.
- 2.3 **ACTIVE THERAPEUTIC EXERCISE PROGRAM** goals should incorporate patient strength, endurance, flexibility, coordination, and education. This includes functional application in vocational or community settings.
- 2.4 **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.
- 2.5 **RE-EVALUATE TREATMENT EVERY 3 TO 4 WEEKS** With respect to Therapy (Active or Passive), if a given treatment or modality is not producing positive results within 3 to 4 weeks, 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.
- 2.6 **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.
- 2.7 **SIX-MONTH TIME FRAME** The prognosis drops precipitously for returning an injured worker to work once he/she has been temporarily totally disabled for more than six months. The emphasis within these guidelines is to move patients along a continuum of care and return to work within a six-month time frame, whenever possible. It is important to note that time frames may not be pertinent to injuries that do not involve work-time loss or are not occupationally related.
- 2.8 **RETURN-TO-WORK** Is therapeutic, assuming the work is not likely to aggravate the basic problem or increase long-term pain. The following physical limitations should be

considered and modified as recommended: lifting, pushing, pulling, crouching, walking, using stairs, bending at the waist, awkward and/or sustained postures, tolerance for sitting or standing, hot and cold environments, data entry and other repetitive motion tasks, sustained grip, tool usage and vibration factors. Even if there is residual chronic pain, return-to-work is not necessarily contraindicated.

The practitioner should understand all of the physical demands of the patient's job position before returning the patient to full duty and should receive clarification of the patient's job duties.

2.9 **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."

2.10 **DELAYED RECOVERY.** The Department recognizes that not all of industrially injured patients will recover within the time lines outlined in this document despite optimal care. Such individuals may require treatments beyond the limits discussed within this document, but such treatment will require clear documentation by the authorized treating practitioner focusing on objective functional gains afforded by further treatment and impact upon prognosis.

3.0 Initial Diagnostic Procedures

The Division 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.

3.1 **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.

3.1.1 **History of Present Injury** A detailed history, taken in temporal proximity to the time of injury should primarily guide evaluation and treatment.

3.1.2 **Past History:**

3.1.3 **Physical Examination:** Should include accepted tests and exam techniques applicable to the area being examined.

3.2 **RADIOGRAPHIC IMAGING** of the lumbosacral spine is a generally accepted, well-established and widely used diagnostic procedure when specific indications based on history and/or physical examination are present. There is some evidence that early radiographic imaging without clear indications is associated with prolonged care, but no difference in functional outcomes. Therefore, it should not be routinely performed without indications. The mechanism of injury and specific indications for the radiograph should be listed on the request form to aid the radiologist and x-ray technician. Suggested indications may include:

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

3.2.2 Age over 55 years;

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

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

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

TITLE 19 LABOR

DELAWARE ADMINISTRATIVE CODE

4

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

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

3.3 **LABORATORY TESTING** Laboratory tests are generally accepted, well-established and widely used procedures. They are, however, rarely indicated at the time of initial evaluation, unless there is suspicion of systemic illness, infection, neoplasia, or underlying rheumatologic disorder, connective tissue disorder, or based on history and/or physical examination. Laboratory tests can provide useful diagnostic information. Tests include, but are not limited to:

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

3.3.2 Erythrocyte sedimentation rate (ESR), rheumatoid factor (RF), antinuclear antigen (ANA), human leukocyte antigen (HLA), and C-reactive protein (CRP), can be used to detect evidence of a rheumatologic, infectious, or connective tissue disorder;

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

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

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

4.0 Follow-Up Diagnostic Imaging and Testing Procedures

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

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

Magnetic resonance imaging (MRI), myelography, or Computed Axial Tomography (CT) scanning following myelography may provide useful information for many spinal disorders. When a diagnostic procedure, in conjunction with clinical information, can provide sufficient information to establish an accurate diagnosis, the second diagnostic procedure will become a redundant procedure. At the same time, a subsequent diagnostic procedure can be a complementary diagnostic procedure if the first or preceding procedures, in conjunction with clinical information, cannot provide an accurate diagnosis. Usually, preference of a procedure over others depends upon availability, a patient's tolerance, and/or the treating practitioner's familiarity with the procedure.

4.1 **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 six weeks of treatment are usually an adequate period of time before an imaging procedure is in order, but the clinician should use judgment in this regard. When indicated, imaging studies can be utilized for further evaluation of the low back, based upon the mechanism of injury, symptoms, and patient history. Prudent choice of a single diagnostic procedure, a complementary combination of procedures, or a

proper sequential order of complementary procedures will help ensure maximum diagnostic accuracy and minimize adverse effect to the patient. When the findings of the diagnostic imaging and testing procedures are not consistent with the clinical examination, the clinical findings should have preference.

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

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

In general, the high field, conventional, MRI provides better resolution. A lower field scan may be indicated when a patient cannot fit into a high field scanner or who is too claustrophobic despite sedation. Inadequate resolution on the first scan may require a second MRI using a different technique.

- 4.1.2 **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.

- 4.1.3 **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.

- 4.1.4 **CT Myelogram** provides more detailed information about relationships between neural elements and surrounding anatomy.

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

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

- 4.1.7 **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.

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

- 4.2 **OTHER TESTS** The following diagnostic procedures in this subsection are listed in alphabetical order, not by importance:

- 4.2.1 Electrodiagnostic Testing:

TITLE 19 LABOR

DELAWARE ADMINISTRATIVE CODE

6

- 4.2.1.1 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.
- In general, EMG and NCS are complementary to imaging procedures such as CT, MRI, and/or myelography or diagnostic injection procedures. Electrodiagnostic studies may provide useful, correlative neuropathophysiological information that would be otherwise unobtainable from the radiologic studies discussed above.
- 4.2.1.2 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.
- 4.2.1.3 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.
- 4.2.1.4 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.
- 4.2.1.5 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.
- 4.2.1.6 Surface EMG in combination with Range of Motion and/or Functional Capacity Evaluation
- This is designed to detect differences between persons with and without low back pain, measuring signals in lumbar flexion which show that painful paraspinal muscles fail to relax fully. It may show aspects of the pathophysiology of muscle activity which advance the scientific understanding of low back pain. The test also purports to determine the significance of disc pathology and the age of an injury. It has not been evaluated in a setting which tests a spectrum of patients commonly seen in clinical practice, using an interpretation which is tested against a diagnostic reference standard. Therefore, it is not suitable as a diagnostic test for low back pain and its use for this purpose is not recommended.
- 4.2.2 Injections — Diagnostic
- 4.2.2.1 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).

4.2.2.2 Indications - Since these procedures are invasive, less invasive or non-invasive procedures should be considered first. Selection of patients, choice of procedure, and localization of the level for injection should be determined by clinical information.

4.2.2.3 The interpretation of the test results are primarily based on functional change, symptom report, and pain response (via a recognized pain scale), before and at an appropriate time period after the injection. The diagnostic significance of the test result should be evaluated in conjunction with clinical information and the results of other diagnostic procedures. Injections with local anesthetics of differing duration may be used to support a diagnosis. In some cases, injections at multiple levels may be required to accurately diagnose low back pain.

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.

4.2.2.4 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. Permanent images are required to verify needle placement. The subspecialty disciplines of the physicians performing the injections may be varied, including, but not limited to: anesthesiology, radiology, surgery, or physiatry. 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.

4.2.2.5 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. Refer to "Injections – Therapeutic" for information on specific therapeutic injections.

4.2.2.5.1 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). 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. 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.

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

4.2.2.5.2 Transforaminal injections are generally accepted and useful in identifying spinal pathology. When performed for diagnosis, small amounts of local anesthetic up to a total volume of 1.0 cc should be used to determine the level of nerve root irritation. A positive diagnostic block should result in a positive diagnostic functional benefit and an 50% reduction in nerve-root generated pain appropriate for the anesthetic used as measured by accepted pain scales (such as a VAS).

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

4.2.2.5.3 Zygapophyseal (Facet) Blocks:

Facet blocks are generally accepted. They may be used diagnostically to direct functional rehabilitation programs. A positive

TITLE 19 LABOR

DELAWARE ADMINISTRATIVE CODE

8

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. Frequency and maximum Duration: Once per suspected level, limited to three levels. May be repeated for confirmation.

4.2.2.5.4 Sacroiliac Joint Injection:

4.2.2.5.4.1 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.

4.2.2.5.4.2 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)

Frequency and Maximum Duration: May be repeated for confirmation.

4.2.3 Provocation Discography:

4.2.3.1 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.

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

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

Discography may show disc degeneration and annular disruption in the absence of low back pain. Discography may also elicit concordant pain in patients with mild and functionally inconsequential back pain. Because patients with mild back pain should not be considered for invasive treatment, discography should not be performed on these patients. In symptomatic patients with annular tears on discography, the side of the tear does not necessarily correlate with the side on which the symptoms occur. The presence of an annular tear does not necessarily identify the tear as the pain generator.

Discography 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.

- 4.2.3.3 Pre-conditions for provocation discography include all of the following:
- 4.2.3.3.1 A patient with functionally limiting, unremitting back and/or leg pain of greater than four months duration in whom conservative treatment has been unsuccessful and in whom the specific diagnosis of the pain generator has not been made apparent on the basis of other 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.
- 4.2.3.3.2 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).
- 4.2.3.3.3 Informed consent regarding the risks and potential diagnostic benefits of discography has been obtained.
- 4.2.3.4 Special Considerations:
- 4.2.3.4.1 Discography should not be performed by the physician expected to perform the therapeutic procedure. The procedure should be carried out by an experienced individual who has received specialized training in the technique of provocation discography.
- 4.2.3.4.2 Discography should be performed in a blinded format that avoids leading the patient with anticipated responses. The procedure should include one or more disc levels thought to be normal or non-painful in order to serve as an internal control. The patient should not know what level is being injected in order to avoid spurious results. Abnormal disc levels may be repeated to confirm concordance.
- 4.2.3.4.3 Sterile technique must be utilized.
- 4.2.3.4.4 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.
- 4.2.3.4.5 The discography should be performed using a manometer to record pressure.
- 4.2.3.4.6 Intradiscal injection of local anesthetic may be carried out after the provocation portion of the examination and the patient's response.
- 4.2.3.4.7 It is recommended that a post-discogram CT be considered as it frequently provides additional useful information about disc morphology or other pathology.
- 4.2.3.5 Reporting of Discography - In addition to a narrative report, the discography report should contain a standardized classification of (a) disc morphology (b) the pain response, and (c) the pressure at which pain is produced. All results should be clearly separated in the report from the narrative portion. Asymptomatic annular tears are common and the concordant pain response is an essential finding for a positive discogram.
- When discography is performed to identify the source of a patient's low-back pain, both a concordant pain response and morphological

TITLE 19 LABOR

DELAWARE ADMINISTRATIVE CODE

10

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.

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

- Grade 0 = Normal Nucleus
- Grade 1 = Annular tear confined to inner one-third of annulus fibrosis.
- Grade 2 = Annular tear extending to the middle third of the annulus fibrosis.
- Grade 3 = Annular tear extending to the outer one-third of the annulus fibrosis.
- Grade 4 = A grade 3 tear plus dissection within the outer annulus to involve more than 30° of the disc circumference.
- Grade 5 = Full thickness tear with extra-annular leakage of contrast, either focal or diffuse.

4.2.3.5.2 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.

4.2.3.5.2.1 Unequivocal Discogenic Pain

- Stimulation of the target disc reproduces concordant pain
- The pain is registered as at least 6 on a 10-point VAS.
- The pain is reproduced at a pressure of less than 15 psi above opening pressure; and
- Stimulation of two adjacent discs does not produce pain at all

4.2.3.5.2.2 Definite Discogenic Pain

- Stimulation of the target disc reproduces concordant pain
- The pain is registered as at least 6 on a 10-point VAS.
- The pain is reproduced at a pressure of less than 15 psi above opening pressure; and
- Stimulation of at least one adjacent disc does not produce pain at all

4.2.3.5.2.3 Highly Probable Discogenic Pain

- Stimulation of the target disc reproduces concordant pain
- That pain is registered as at least 6 on a 10-point VAS.
- That the pain is reproduced at a pressure of less than 50 psi above opening pressure; and
- Stimulation of two adjacent discs does not produce pain at all

4.2.3.5.2.4 Probable Discogenic Pain

- Stimulation of the target disc reproduces concordant pain
- That pain is registered as at least 6 on a 10-point VAS.
- The pain is reproduced at a pressure of less than 50 psi above opening pressure; and
- Stimulation of one adjacent disc does not produce pain at all, and stimulation of another adjacent discs at greater than 50 psi, produces pain, but the pain is not concordant.

Multiple combinations of factors are possible. However, if the patient does not qualify for at least a 'Probable Discogenic Pain' level, then the discogram should 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.

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

5.0 Therapeutic Procedures – Non-Operative

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 for detailed information.

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. Providers should provide and document education to the patient. No treatment plan is complete without addressing issues of individual and/or group patient education as a means of facilitating self-management of symptoms.

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.

- 5.1 **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 MD, DO or DC with appropriate training.

- 5.1.1 **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.

- 5.1.2 **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.

- 5.1.3 **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.

TITLE 19 LABOR

DELAWARE ADMINISTRATIVE CODE

12

Time to produce effect: 3 to 6 treatments Frequency: 1 to 3 times per week
Maximum course duration: 14 treatments (one course)

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.

5.1.4 **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.

5.2 **BIOFEEDBACK** is a form of behavioral medicine that helps patients learn self-awareness and self-regulation skills for the purpose of gaining greater control of their physiology, such as muscle activity, brain waves, and measures of autonomic nervous system activity. Electronic instrumentation is used to monitor the targeted physiology and then displayed or fed back to the patient visually, auditorially, or tactilely, with coaching by a biofeedback specialist. Biofeedback is provided by clinicians certified in biofeedback and/or who have documented specialized education, advanced training, or direct or supervised experience qualifying them to provide the specialized treatment needed (e.g., surface EMG, EEG, or other).

Treatment is individualized to the patient's work-related diagnosis and needs. Home practice of skills is required for mastery and may be facilitated by the use of home training tapes. The ultimate goal of biofeedback treatment is to normalize physiology to the pre-injury status to the extent possible, and involves transfer of learned skills to the workplace and daily life. Candidates for biofeedback therapy or training must be motivated to learn and practice biofeedback and self-regulation techniques. Indications for biofeedback include individuals who are suffering from musculoskeletal injury in which muscle dysfunction or other physiological indicators of excessive or prolonged stress response affects and/or delays recovery. Other applications include training to improve self-management of emotional stress/pain responses such as anxiety, depression, anger, sleep disturbance, and other central and autonomic nervous system imbalances. Biofeedback is often used in conjunction with other treatment modalities.

Time to produce effect: 3 to 4 visits

Frequency: 1 to 2 times per week

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.

5.3 **INJECTIONS — THERAPEUTIC**

5.3.1 **Therapeutic Spinal Injections:**

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.

Special Considerations - For all injections (excluding trigger point), multi-planar fluoroscopic guidance during procedures is required to document technique and needle placement, and should be performed by a physician experienced in the procedure. Permanent images are required to verify needle replacement. The subspecialty disciplines of the physicians performing injections may be varied, including, but not

limited to: anesthesiology, radiology, surgery, or physiatry. The practitioner should document hands-on training through workshops of the type offered by organizations such as the International Spine Intervention Society (ISIS) and/or completed fellowship training in pain medicine with interventional training. They must also be knowledgeable in radiation safety.

5.3.1.1 Epidural Steroid Injection (ESI)

5.3.1.1.1 Description - Epidural steroid injections are injections of corticosteroid into the epidural space. The purpose of ESI is to reduce pain and inflammation in the acute or sub-acute phases of injury. ESI uses three approaches: transforaminal, interlaminar (midline), and caudal.

5.3.1.1.2 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.

5.3.1.1.3 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.

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.

Maximum duration: Six treatments (a treatment may include injections at one or two levels) may be done in one 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.

5.3.1.2 Zygapophyseal (Facet) Injection

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

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

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).

Maximum Duration: 4 per level per year. Maximum three levels

5.3.1.2.3 Sacroiliac Joint Injection:

5.3.1.2.3.1 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. Long-term therapeutic effect has not yet been established.

5.3.1.2.3.2 Indications - Primarily diagnostic to rule out sacroiliac joint dysfunction vs. other

TITLE 19 LABOR

DELAWARE ADMINISTRATIVE CODE

14

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).

Maximum duration: 4 injections per year.

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

5.3.2 Radio Frequency Medial Branch Neurotomy/facet rhizotomy:

5.3.2.1 Description - A procedure designed to denervate the facet joint by ablating the corresponding sensory medial branches. Continuous percutaneous radiofrequency is the method generally used.

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

5.3.2.2 Indications - Those patients with significant, facetogenic pain.

Individuals should have met all of the following indications: Pain of well-documented facet origin, unresponsive to active and/or passive therapy. It is generally recommended that this procedure not be performed until three months of conservative therapy have been completed. All patients should continue appropriate exercise with functionally directed rehabilitation. Active treatment, which patients will have had prior to the procedure, will frequently require a repeat of the sessions previously ordered. All patients should have a successful response to a diagnostic medial nerve branch block and a separate comparative block. To be a positive diagnostic block the patient should report a reduction of pain of 50% or greater from baseline for the length of time appropriate for the local anesthetic used. It is suggested that this be recorded on a form. 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.

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

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

5.3.3 **Sacro-iliac (SI) Joint Radiofrequency Denervation:** is a denervation of the SI joint. This procedure is not recommended.

5.3.4 **Trigger Point Injections and Dry Needling Treatment:**

5.3.4.1 Description - Trigger point injections are a generally accepted treatment. Trigger point treatment can consist of dry needling or injection of local anesthetic, with or without corticosteroid, into highly localized, extremely sensitive bands of skeletal muscle fibers that produce local and referred pain when activated. Injection efficacy may be enhanced if injections are immediately followed by myofascial therapeutic interventions, such as vapor-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.

5.3.4.2 Indications - Trigger point injections may be used to relieve myofascial pain and facilitate active therapy and stretching of the affected areas. They are to be used as an adjunctive treatment in combination with other treatment modalities such as functional restoration programs. Trigger point injections should be utilized primarily for the purpose of facilitating functional progress. Patients should continue in therapeutic exercise program as tolerated throughout the time period they are undergoing intensive myofascial interventions. Myofascial pain is often associated with other underlying structural problems and any abnormalities need to be ruled out prior to injection.

Trigger point injections are indicated in those patients where well circumscribed trigger points have been consistently observed. Generally, these injections are not necessary unless consistently observed trigger points are not responding to specific, noninvasive, myofascial interventions within approximately a 6-week time frame. However, trigger point injections may be occasionally effective when utilized in the patient with immediate, acute onset of low back pain.

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

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

5.3.5 **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.

5.3.6 **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

TITLE 19 LABOR DELAWARE ADMINISTRATIVE CODE

16

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

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

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

- 5.4 **MEDICATIONS** use in the treatment of low back injuries is appropriate for controlling acute and chronic pain and inflammation. Use of medications will vary widely due to the spectrum of injuries from simple strains to post-surgical healing. 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 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.

The following are listed in alphabetical order:

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

- 5.4.2 **Muscle Relaxants:** are appropriate for muscle spasm with pain. There is strong evidence that muscle relaxants are more effective than placebo for providing short-term pain relief in acute low back pain. When prescribing these agents, physicians must seriously consider side effects of drowsiness or dizziness and the fact that benzodiazepines may be habit-forming

- 5.4.3 **Narcotics:** should be primarily reserved for the treatment of severe low back pain. In mild to moderate cases of low back pain, narcotic medication should be used cautiously on a case-by-case basis. Adverse effects include respiratory depression, the development of physical, and impaired alertness.

Narcotic medications should be prescribed with strict time, quantity, and duration guidelines, and with definitive cessation parameters. Pain is subjective in nature and should be evaluated using a scale to rate effectiveness of the narcotic prescribed.

- 5.4.4 **Nonsteroidal Anti-Inflammatory Drugs (NSAIDs):** are useful for pain and inflammation. In mild cases, they may be the only drugs required for analgesia. There are several classes of NSAIDs, and the response of the individual injured worker to a specific medication is unpredictable. For this reason, a range of NSAIDs may be tried in each case with the most effective preparation being continued. Patients should be closely

monitored for adverse reactions. Naproxen sodium does not appear to be associated with increased risk of vascular events. Administration of proton pump inhibitors, Histamine 2 Blockers or prostaglandin analog misoprostol along with these NSAIDs may reduce the risk of duodenal and gastric ulceration. Intervals for metabolic screening are dependent upon the patient's age, general health status and should be within parameters listed for each specific medication. Complete Blood Count (CBC), and liver and renal function should be monitored in patients on chronic NSAIDs and initially when indicated.

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

COX-2 inhibitors are more recent NSAIDs and differ in adverse side effect profiles from the traditional NSAIDs. The major advantages of selective COX-2 inhibitors over traditional NSAIDs are that they have less gastrointestinal toxicity and no platelet effects.

COX-2 inhibitors 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.

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

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

As a general rule, physicians should access the patient's prior history of substance abuse or depression prior to prescribing any of these agents. Due to the habit-forming potential of the benzodiazepines and other drugs found in this class, they are not routinely recommended.

5.4.6 **Tramadol:** is useful in relief of low back pain and has been shown to provide pain relief equivalent to that of commonly prescribed NSAIDs. Although Tramadol may cause impaired alertness, it is generally well tolerated, does not cause gastrointestinal ulceration, or exacerbate hypertension or congestive heart failure.

5.5 OCCUPATIONAL REHABILITATION PROGRAMS

5.5.1 **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.

5.5.1.1 **Work Conditioning/Simulation** This program may begin once a patient is out of the acute phase of injury and will be able to tolerate this program.

These programs are usually initiated after the acute phase has been completed and offered at any time throughout the recovery phase. Work conditioning should be initiated when imminent return of a patient to modified or full duty is not an option, but the prognosis for returning the patient to work at completion of the program is at least fair to good. The need for work place simulation should be based upon the results of a Functional Capacity Evaluation and/or Jobsite Analysis.

Length of visit: 1 to 4 hours per day.

TITLE 19 LABOR

DELAWARE ADMINISTRATIVE CODE

18

Frequency: 2 to 5 visits per week

Maximum duration: 8 weeks. Participation in a program beyond six weeks must

be documented with respect to need and the ability to facilitate positive

symptomatic or functional gains.

5.5.1.2

Work Hardening

Work Hardening is an interdisciplinary program addressing a patient's employability and return to work. It includes a progressive increase in the number of hours per day that a patient completes work simulation tasks until the patient can tolerate a full workday. This is accomplished by addressing the medical, behavioral, physical, functional, and vocational components of employability and return-to-work.

This can include a highly structured program involving a team approach or can involve any of the components thereof. The interdisciplinary team should, at a minimum, be comprised of a qualified medical director who is board certified with documented training in occupational rehabilitation; team physicians having experience in occupational rehabilitation; occupational therapist; physical therapist; case manager; and psychologist. As appropriate, the team may also include: chiropractor, RN, vocational specialist or Certified Biofeedback Therapist.

Length of visit: Up to 8 hours/day

Frequency: 2 to 5 visits per week

Maximum duration: 8 weeks. Participation in a program beyond six weeks must

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

5.5.1.3

Spinal Cord Programs

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

This can include a highly structured program involving a team approach or can involve any of the components thereof. The interdisciplinary team should, at a minimum, be comprised of a qualified medical director who is board certified and trained in rehabilitation, a case manager, occupational therapy, physical therapy, psychologist, rehabilitation RN and MD, and therapeutic recreation specialist. As appropriate, the team may also include: rehabilitation counselor, respiratory therapist, social worker, or speech-language pathologist.

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.

5.6 ORTHOTICS

5.6.1 **Foot Orthoses and Inserts:** are accepted interventions for spinal disorders that are due to aggravated mechanical abnormalities, such as leg length discrepancy, scoliosis, or lower extremity misalignment. Shoe insoles or inserts may be effective for patients with acute low back problems who stand for prolonged periods of time.

5.6.2 **Lumbar Support Devices:** include backrests for chairs and car seats. Lumbar supports may provide symptomatic relief of pain and movement reduction in cases of chronic low back problems.

5.6.3 **Lumbar Corsets and Back 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.

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

5.7 **PATIENT EDUCATION** No treatment plan is complete without addressing issues of individual and/or group patient education as a means of prolonging the beneficial effects of treatment, as well as facilitating self-management of symptoms and injury prevention. The patient should be encouraged to take an active role in the establishment of functional outcome goals. They should be educated on their specific injury, assessment findings, and plan of treatment. Instruction on proper body mechanics and posture, positions to avoid, self-care for exacerbation of symptoms, and home exercise should also be addressed.

Time to produce effect: Varies with individual patient

Frequency: Should occur at every visit.

5.8 **RESTRICTION OF ACTIVITIES** Continuation of normal daily activities is the recommendation for acute and chronic low back pain without neurologic symptoms. There is good evidence against the use of bed rest in cases without neurologic symptoms. Bed rest may lead to de-conditioning and impair rehabilitation. Modified return-to-work is almost always more efficacious and rarely contraindicated in the vast majority of injured workers with low back pain.

5.9 **RETURN-TO-WORK** Early return-to-work should be a prime goal in treating occupational injuries given the poor return-to-work prognosis for an injured worker who has been out of work for more than six months. It is imperative that the patient be educated regarding the benefits of return-to-work, work restrictions, and follow-up if problems arise. When attempting to return a patient to work after a specific injury, clear objective physical capabilities of the injured worker should be outline on the appropriate form. An accurate job description with detailed physical duty requirements is often necessary to assist the physician in making return-to-work recommendations.

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

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

Compliance with Activity Restrictions: In some cases, compliance with restriction of activity levels may require a complete job site evaluation, a functional capacity evaluation (FCE) or other special testing.

5.10 **THERAPY — PASSIVE** Most of the following passive therapies and modalities are generally accepted methods of care for a variety of work-related injuries. Passive therapy

TITLE 19 LABOR

DELAWARE ADMINISTRATIVE CODE

20

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.

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 twelve visits or three weeks after the onset of treatment. Reimbursement for passive modalities only after the first twelve visits or three weeks of treatment without clear evidence of Active Interventions will require supportive documentation.

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:

- 5.10.1 **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.

Time to produce effect: 2 to 4 treatments

Maximum duration: 14 visits

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

Time to produce effect: 1 to 4 treatments

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

Maximum duration: 8 visits per body region

- 5.10.3 **Manipulation:** Is generally accepted, well-established and widely used therapeutic intervention for low back pain. Manipulative Treatment (not therapy) is defined as the therapeutic application of manually guided forces by an operator to improve physiologic function and/or support homeostasis that has been altered by the injury or occupational disease, and has associated clinical significance.

High velocity, low amplitude (HVLA) technique, chiropractic manipulation, osteopathic manipulation, muscle energy techniques, counter strain, and non-force techniques are all types of manipulative treatment. This may be applied by osteopathic

physicians (D.O.), chiropractors (D.C.), properly trained physical therapists (P.T.), or properly trained medical physicians. Under these different types of manipulation exist many subsets of different techniques that can be described as a) direct- a forceful engagement of a restrictive/pathologic barrier, b) indirect- a gentle/non-forceful disengagement of a restrictive/pathologic barrier, c) the patient actively assists in the treatment and d) the patient relaxing, allowing the practitioner to move the body tissues. When the proper diagnosis is made and coupled with the appropriate technique, manipulation has no contraindications and can be applied to all tissues of the body. Pre-treatment assessment should be performed as part of each manipulative treatment visit to ensure that the correct diagnosis and correct treatment is employed.

High velocity, low amplitude (HVLA) manipulation is performed by taking a joint to its end range of motion and moving the articulation into the zone of accessory joint movement, well within the limits of anatomical integrity. Indications for manipulation include joint pain, decreased joint motion, and joint adhesions. Contraindications to HVLA manipulation include joint instability, fractures, severe osteoporosis, infection, metastatic cancer, active inflammatory arthritides, aortic aneurysm, and signs of progressive neurologic deficits.

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

Frequency: Up to 3 times per week for the first 4 weeks as indicated by the severity of involvement and the desired effect, then up to 2 treatments per week for the next 4 weeks. For further treatments, twice per week or less to maintain function.

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.

5.10.3.1 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.

Time to produce effect: 4 to 6 treatments

Frequency: 2 to 3 times per week

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

5.10.4 **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

TITLE 19 LABOR

DELAWARE ADMINISTRATIVE CODE

22

pain population, although no studies have demonstrated its efficacy for this set of patients.

Time to produce effect: Immediate

Frequency: 1 to 3 times per week

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

- 5.10.5 **Mobilization (Joint):** is a generally well-accepted treatment. Mobilization is passive movement involving oscillatory motions to the vertebral segment(s). The passive mobility is performed in a graded manner (I, II, III, IV, or V), which depicts the speed and depth of joint motion during the maneuver. For further discussion on Level V joint mobilization please see section on HVLA manipulation [Refer to section 12. d.]. It may include skilled manual joint tissue stretching. Indications include the need to improve joint play, segmental alignment, improve intracapsular arthrokinematics, or reduce pain associated with tissue impingement. Mobilization should be accompanied by active therapy. For Level V mobilization contraindications include joint instability, fractures, severe osteoporosis, infection, metastatic cancer, active inflammatory arthritides, aortic aneurysm, and signs of progressive neurologic deficits.

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

Frequency: Up to 3 times per week for the first 4 weeks as indicated by the severity of involvement and the desired effect, then up to 2 treatments per week for the next 4 weeks. For further treatments twice per week or less to maintain function.

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.

RE-EVALUATE TREATMENT EVERY 3 TO 4 WEEKS If a given treatment or modality is not producing positive results within 3 to 4 weeks, the treatment may be either modified or discontinued. Reconsideration of diagnosis should also occur in the event of poor response to a seemingly rational intervention.

CPT codes 97124 and 97140 cannot exceed 36 visits in combination

- 5.10.6 **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.

Maximum duration: 36 visits

RE-EVALUATE TREATMENT EVERY 3 TO 4 WEEKS If a given treatment or modality is not producing positive results within 3 to 4 weeks, the treatment may be either modified or discontinued. Reconsideration of diagnosis should also occur in the event of poor response to a seemingly rational intervention.

CPT codes 97124 and 97140 cannot exceed 36 visits in combination.

- 5.10.7 **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.

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

Time to produce effect:

Immediate

Frequency: 2 to 5 times per week

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

- 5.10.9 **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.

- 5.10.10 **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.

Time to produce effect: 1 to 3 sessions up to 30 minutes. If response is negative after 3 treatments, discontinue this modality. Frequency: 2 to 3 times per week. A home lumbar traction unit can be purchased if therapy proves effective. Maximum duration: 24 visits

- 5.10.11 **Transcutaneous Electrical Nerve Stimulation (TENS):** is a generally accepted treatment. TENS should include at least one instructional session for proper application and use. Indications include muscle spasm, atrophy, and decreased circulation and pain control. Minimal TENS unit parameters should include pulse rate, pulse width and amplitude modulation. Consistent, measurable functional improvement should be documented prior to the purchase of a home unit.

Time to produce effect: Immediate

Frequency: Variable

- 5.10.12 **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.

Time to produce effect: 6 to 15 treatments

Frequency: 3 times per week

Maximum duration: 18 visits

TITLE 19 LABOR

DELAWARE ADMINISTRATIVE CODE

24

5.10.13 **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.**

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

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

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

Time to produce effect: 4 to 5 treatments

Maximum duration: 10 visits

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

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

Time to produce effect: 4 to 5 treatments

Frequency: 3 to 5 times per week

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.

- 5.11.3 **Functional Activities:** are well-established interventions which involve the use of therapeutic activity to enhance mobility, body mechanics, employability, coordination, balance, and sensory motor integration.

Time to produce effect: 4 to 5 treatments

Frequency: 3 to 5 times per week

Maximum duration: 24 visits

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

- 5.11.4 **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)

Time to produce effect: 2 to 6 treatments

Frequency: 3 times per week

Maximum duration: 14 visits inclusive of electrical muscle stimulation codes if

beneficial provide with home unit.

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

Time to produce effect: 2 to 6 treatments

Frequency: 3-5 times per week

Maximum duration: 30 visits

- 5.11.6 **Therapeutic Exercise:** is a generally well-accepted treatment. Therapeutic exercise, with or without mechanical assistance or resistance, may include isoinertial, isotonic, isometric and isokinetic types of exercises. Indications include the need for cardiovascular fitness, reduced edema, improved muscle strength, improved connective tissue strength and integrity, increased bone density, promotion of circulation to enhance soft tissue healing, improvement of muscle recruitment, improved proprioception, and coordination, increased range of motion. Therapeutic exercises are used to promote normal movement patterns, and can also include complementary/alternative exercise movement therapy (with oversight of a physician or appropriate healthcare professional).

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

Time to produce effect: 2 to 6 treatments

Frequency: 3 to 5 times per week

Maximum duration: 30 visits

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

TITLE 19 LABOR

DELAWARE ADMINISTRATIVE CODE

26

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

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

6.0 Therapeutic Procedures - Operative

All operative interventions must be based upon positive correlation of clinical findings, clinical course, and diagnostic tests. A comprehensive assimilation of these factors must lead to a specific diagnosis with positive identification of pathologic condition(s). It is important to consider non-physiologic modifiers of pain presentation or non-operative conditions mimicking radiculopathy or instability prior to consideration of elective surgical intervention.

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

In general, if the program of non-operative treatment fails, operative treatment is indicated when:

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

Surgical evaluation for simple decompression of patients with herniated nucleus pulposus and sciatica should occur within 6 to 12 weeks after injury at the latest, within the above stated contingencies. For patients with true, refractory mechanical low back pain in whom fusion is being considered, it is recommended that a surgical evaluation or interventions occur within 4 months following injury.

Spinal decompression surgeries and fusion have re-operation rates of approximately 10% or more over the following five years. Re-operation is indicated only when the 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. "Outcomes" refer to the patient's ability to improve functional tolerances such as sitting, standing, walking, strength, endurance, and/or vocational status and pain level. 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.

Every post-operative patient should be involved in an active treatment program. The non-surgical rehab guidelines listed above do not apply to post-operative rehabilitation and work conditioning. Interdisciplinary interventions should be strongly considered post-operatively in any patient not making functional progress within expected time frames.

6.1

DISCECTOMY AND NERVE ROOT DECOMPRESSION

6.1.1 **Description:** To enter into and partially remove the disc and/or Decompress Nerve Root.

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

6.1.3 **Post-Operative Therapy:** A formal physical therapy program should be implemented post-operatively. Active treatment, which patients should have had prior to surgery, will frequently require a repeat of the visits previously ordered. The non-surgical rehab guidelines listed above do not apply to post-operative rehabilitation and work conditioning

6.2 PERCUTANEOUS DISCECTOMY

6.2.1 **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.

6.2.2 **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.

6.3 LAMINOTOMY/LAMINECTOMY/FORAMENOTOMY/FACETECTOMY

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

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

6.3.3 **Post-Operative Therapy:** A formal rehab program should be implemented post-operatively. 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 restoration of ROM, core stabilization, strengthening, and endurance is recommended. 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.

6.4 SPINAL FUSION

6.4.1 **Description:** Production of a rigid connection between two or more adjacent vertebrae.

6.4.2 **Surgical Indications:** A timely decision-making process is recommended when considering patients for possible fusion. For chronic low back problems, fusion should not be considered within the first 4 months of symptoms, except for fracture, dislocation, recurrent herniation, or gross instability

Indications for spinal fusion may include:

6.4.2.1 Neural arch defect – Spondylolytic spondylolisthesis, congenital unilateral neural arch hypoplasia.

6.4.2.2 Segmental Instability - Excessive motion, as in degenerative spondylolisthesis, surgically induced segmental instability.

6.4.2.3 Primary Mechanical Back Pain/Functional Spinal Unit Failure - Multiple pain generators objectively involving two or more of the following: (a) internal disc disruption (poor success rate if more than two disc

TITLE 19 LABOR DELAWARE ADMINISTRATIVE CODE

28

involved), (b) painful motion segment, as in annular tears, (c) disc resorption, (d) facet syndrome, and or (e) ligamentous tear. (f) Degenerative disc disease.

- 6.4.2.4 Revision surgery for failed previous operation(s) if significant functional gains are anticipated.
- 6.4.2.5 History of multiple recurrent herniated discs.
- 6.4.3 **Pre-operative Surgical Indications:** Required pre-operative clinical surgical indications for spinal fusion include all of the following:
 - 6.4.3.1 Planned fusion to exceed two levels requires confirmatory second opinion.
 - 6.4.3.2 For any potential fusion surgery, it is recommended that the injured worker be encouraged to refrain from smoking for at least six weeks prior to surgery and during the period of fusion healing. Because smokers have a higher risk of non-union and higher post-operative costs, it is recommended that insurers cover a smoking cessation program peri-operatively.
- 6.4.4 **Post-operative Therapy:** A formal rehab program should be implemented post-operatively. 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 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
- 6.4.5 **Return-to-Work:** Barring complications, patients responding favorably to spinal fusion may be able to return to sedentary-to-light work within 6 to 12 weeks post-operatively, light-to-medium work within 6 to 9 months post-operatively and medium-to-medium/heavy work within 6 to 12 months post-operatively. Patients requiring fusion whose previous occupation involved heavy-to-very-heavy labor should be considered for vocational assessment as soon as reasonable restrictions can be predicted. The practitioner should release the patient with specific physical restrictions and should obtain a clear job description from the employer, if necessary. Once an injured worker is off work greater than 6 months, the functional prognosis with or without fusion becomes guarded for that individual.
- 6.5 **SACROILIAC JOINT FUSION**
 - 6.5.1 **Description:** Use of bone grafts, sometimes combined with metal devices, to produce a rigid connection between two or more adjacent vertebrae providing symptomatic instability as a part of major pelvic ring disruption.
 - 6.5.2 **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.
- 6.6 **IMPLANTABLE SPINAL CORD STIMULATORS** are reserved for those low back pain patients with pain of greater than 6 months duration who have not responded to the standard

non-operative or operative interventions previously discussed within this document. Refer to Division's Chronic Pain Disorder Medical Treatment Guidelines.

6.7 **INTRADISCAL ELECTROTHERMAL ANNULOPLASTY (IDEA) (more commonly called IDET, or Intradiscal Electrothermal therapy)**

6.7.1 **Description:** An outpatient non-operative procedure. A wire is guided into the identified painful disc using fluoroscopy. The wire is then heated at the nuclear annular junction within the disc. Physicians performing this procedure must have been trained in the procedure and should have performed at least 25 prior discograms. Prior authorization is required for IDET.

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

The candidate should meet the following criteria:

6.7.2.1 Age not above 60 or under 18; and

6.7.2.2 Normal neurological exam; and

6.7.2.3 No evidence of nerve root compression on MRI; and

6.7.2.4 Concordant pain reproduced with provocation discography (low pressure); and

6.7.2.5 Functionally limiting low back pain far in excess of leg pain for at least 6 months; and

6.7.2.6 No evidence of inflammatory arthritis, spinal conditions mimicking low back pain, moderate to severe spinal stenosis, spinal instability, disc herniation, or medical or metabolic diseases precluding follow-up rehabilitation; and

6.7.2.7 Disc height greater than 50% of adjacent normal disc;
and

6.7.2.8 No previous IDET procedure at the same level.

6.7.3 **Post-Procedure Therapy:** Some cases may require epidural injection after the IDET procedure has been performed. A corset should be used for the first 6 weeks. Sitting upright is limited to 30 to 45 minutes for the first two weeks. A formal physical therapy program should be implemented post-operatively. Some patients may benefit from several occupational therapy visits to improve performance of ADLs. Rehabilitation may take as long as 6 months and include stretching during the first month, floor exercises in the second month, 3 to 5 consecutive months of progressive exercise program, and sport activities in the 5th and 6th months as tolerated. The goals of the therapy program should include instruction in a long-term home-based exercise program. The non-surgical physical therapy guidelines listed above do not apply to post-operative rehabilitation and work conditioning

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

6.8 **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

TITLE 19 LABOR

DELAWARE ADMINISTRATIVE CODE

30

reduce intradiscal pressure. Its effectiveness has not been shown. Laser discectomy is not recommended.

6.9 ARTIFICIAL LUMBAR DISC REPLACEMENT

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

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

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

6.9.2 **Surgical Indications:**

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

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

6.9.3 **Contraindications:**

Significant spinal deformity/scoliosis Facet joint arthrosis Spinal instability Deficient posterior elements Infection Any contraindications to an anterior abdominal approach (including multiple prior abdominal procedures) Previous compression or burst fracture at the surgical level Spinal canal stenosis Spondylolysis Spondylolisthesis greater than 3 mm Osteoporosis or any metabolic bone disease Chronic steroid use or use of other medication known to interfere with bone or soft tissue healing Autoimmune disorder Allergy to device components/materials Morbid obesity (e.g., body/mass index [BMI] of greater than 40, over 100 pounds overweight) Active malignancy

6.9.4 **Post-operative Therapy:** 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 weeks in uncomplicated cases. The goals of the therapy program should include instruction in a long-term home based exercise program. The non-surgical therapy guidelines listed above do not apply to post-operative rehabilitation and work conditioning

6.10 KYPHOPLASTY

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

6.10.2 **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 one month of the fracture, since the elevation of the endplates may be more readily achieved than when the procedure is delayed.

6.10.3 **Surgical Indications:** Kyphoplasty is an accepted treatment for the following indications:

Compression fracture vertebral height loss between 20% and 85% Vertebral height restoration.

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

6.10.4 **Contraindications:**

The presence of neurologic compromise related to fracture
 High-velocity fractures with a significant burst component
 Significant posterior vertebral body wall fracture
 Severe vertebral collapse (vertebra plana)
 Infection, and
 Coagulopathy

6.11 VERTEBROPLASTY

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

6.11.2 **Indications:**

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

TITLE 19 LABOR

DELAWARE ADMINISTRATIVE CODE

32

6.11.3 **Contraindications:**

The presence of neurologic compromise related to the fracture; High velocity fractures with a significant burst component. Posterior vertebral body wall fracture; Severe vertebral collapse (vertebra plana); and Infection; and Coagulopathy

6.12 **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.

6.13 **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.

6.14 **EPIDUROSCOPY AND EPIDURAL LYSIS OF ADHESIONS** (Refer to Injections-Therapeutic).

6.15 **INTRAOPERATIVE MONITORING** is a common intraoperative electrodiagnostic technique that may include somatosensory evoked potentials (SSEP), motor evoked potentials (MEP), or pedicle screw monitoring. The monitoring procedure may be used to evaluate spinal cord integrity and screw placement during the operative procedure. The use of intraoperative monitoring can be anticipated to become more common as percutaneous spinal procedures gain greater acceptance.

13 DE Reg. 1558 (06/01/10)

7.0 General Guidelines

7.1 **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:

7.1.1 The operation per se

7.1.2 Local infiltration, metacarpal/metatarsal/digital block or topical anesthesia

7.1.3 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

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

7.1.5 Writing orders

7.1.6 Evaluating the patient in the post anesthesia recovery area

7.1.7 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.

7.1.8 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.

7.2 **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

7.3 **Surgical Assistant**

7.3.1 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 twenty percent (20%) of the maximum reimbursement allowance (MRA) for the procedure(s).

7.3.2 Registered Nurse Surgical Assistant or Physician Assistant

7.3.2.1 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.).

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

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

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

7.4 **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 one 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 one or two muscles or 20553 when three or more muscles are involved.

7.5 **Intervertebral Biomechanical Device(s) and Use of Code 22851**

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 one 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 dependant 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

**TITLE 19 LABOR
DELAWARE ADMINISTRATIVE CODE**

34

device. Surgeons utilizing generic non-machined bony allografts or autografts are referred to code sets 20930–20931, 20936–20938 respectively.)

7.6 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.

7.7 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.

7.8 External Spinal Stimulators Post Fusion

7.8.1 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.

7.8.1.1 Patient has had a previously failed spinal fusion, and/or

7.8.1.2 Patient is scheduled for revision or repair of pseudoarthrosis, and/or

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

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

7.8.3 The external spinal stimulator will be reimbursed by report (BR).

7.8.4 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.

7.8.5 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)