

RULE 17, EXHIBIT 3

Thoracic Outlet Syndrome Medical Treatment Guidelines

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Department of Labor and Employment

Division of Workers' Compensation

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Rule 17, EXHIBIT 3

THORACIC OUTLET SYNDROME MEDICAL TREATMENT GUIDELINES

A. INTRODUCTION

This document has been prepared by the Colorado Department of Labor and Employment, Division of Workers' Compensation (Division) and should be interpreted within the context of guidelines for physicians/providers treating injured workers with upper extremity involvement pursuant to the Colorado's Workers' Compensation Act.

Although the primary purpose of this document is advisory and educational, these guidelines are enforceable under the Workers' Compensation Rules of Procedure, 7 CCR 1101-3. The Division recognizes that acceptable medical practice may include deviations from these guidelines, as individual cases dictate. Therefore, these guidelines are not relevant as evidence of a provider's legal standard of professional care.

To properly utilize this document, the reader should not skip or overlook any sections.

B. GENERAL GUIDELINES PRINCIPLES

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

- 1. APPLICATION OF GUIDELINES:** The Division provides procedures to implement medical treatment guidelines and to foster communication to resolve disputes among the provider, payer, and patient through the Workers' Compensation Rules of Procedure. In lieu of more costly litigation, parties may wish to seek administrative dispute resolution services through the Division or the Office of Administrative Courts.
- 2. EDUCATION:** Education of the patient and family, as well as the employer, insurer, policy makers and the community should be the primary emphasis in the treatment of chronic pain and disability. Currently, practitioners often think of education last, after medications, manual therapy, and surgery. Practitioners must implement strategies, to educate patients, employers, insurance systems, policy makers, and the community as a whole. An education-based paradigm should always start with inexpensive communication providing reassuring and evidence-based information to the patient. More in-depth patient education is currently a component of treatment regimens which employ functional restorative, preventive, and rehabilitative programs. No treatment plan is complete without addressing issues of individual and/or group patient education as a means of facilitating self-management of symptoms and prevention.
- 3. INFORMED DECISION MAKING:** Providers should implement informed decision making as a crucial element of a successful treatment plan. Patients, with the assistance of their health care practitioner, should identify their personal and professional functional goals of treatment at the first visit. Progress towards the individual's identified functional goals should be addressed by all members of the health care team at subsequent visits and throughout the established treatment plan. Nurse case managers, physical therapists, and other members of the health care team play an integral role in informed decision making and achievement of functional goals. Patient education and informed decision making should facilitate self-management of symptoms and prevention of further injury.
- 4. TREATMENT PARAMETER DURATION:** Time frames for specific interventions commence once treatments have been initiated, not on the date of injury. Obviously, duration will be impacted by patient compliance, as well as availability of services. Clinical judgment may substantiate the need to accelerate or decelerate the time frames discussed in this document.
- 5. ACTIVE INTERVENTIONS:** emphasizing patient responsibility, such as therapeutic exercise and/or functional treatment, are generally emphasized over passive modalities, especially as treatment progresses. Generally, passive and palliative interventions are viewed as a means to facilitate progress in an active rehabilitation program with concomitant attainment of objective functional gains.

- 6.** **ACTIVE THERAPEUTIC EXERCISE PROGRAM:** goals should incorporate patient strength, endurance, flexibility, coordination, and education. This includes functional application in vocational or community settings.
- 7.** **POSITIVE PATIENT RESPONSE:** results are defined primarily as functional gains that can be objectively measured. Objective functional gains include, but are not limited to, positional tolerances, range of motion (ROM), strength, endurance, activities of daily living, cognition, psychological behavior, and efficiency/velocity measures that can be quantified. Subjective reports of pain and function should be considered and given relative weight when the pain has anatomic and physiologic correlation. Anatomic correlation must be based on objective findings.
- 8.** **RE-EVALUATE TREATMENT EVERY 3 TO 4 WEEKS:** If a given treatment or modality is not producing positive results within three to four weeks, the treatment should be either modified or discontinued. Before discontinuing the treatment, the provider should have a detailed discussion with the patient to determine the reason for failure to produce positive results. Reconsideration of diagnosis should also occur in the event of a poor response to a seemingly rational intervention.
- 9.** **SURGICAL INTERVENTIONS:** should be contemplated within the context of expected functional outcome and not purely for the purpose of pain relief. The concept of “cure” with respect to surgical treatment by itself is generally a misnomer. All operative interventions must be based upon positive correlation of clinical findings, clinical course, and diagnostic tests. A comprehensive assimilation of these factors must lead to a specific diagnosis with positive identification of pathologic conditions.
- 10.** **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.
- 11.** **RETURN-TO-WORK:** is therapeutic, assuming the work is not likely to aggravate the basic problem or increase long-term pain. The practitioner must provide specific physical limitations and the patient should never be released to “sedentary” or “light duty.” The following physical limitations should be considered and modified as recommended: lifting, pushing, pulling, crouching, walking, using stairs, bending at the waist, awkward and/or sustained postures, tolerance for sitting or standing, hot and cold environments, data entry and other repetitive motion tasks, sustained grip, tool usage and vibration factors. Even if there is residual chronic pain, return-to-work is not necessarily contraindicated.

The practitioner should understand all of the physical demands of the patient’s job position before returning the patient to full duty and should request clarification of the patient’s job duties. Clarification should be obtained from the employer or, if necessary, including, but not limited to, an occupational health nurse, occupational therapist, vocational rehabilitation specialist, or an industrial hygienist.

12. DELAYED RECOVERY: Strongly consider a psychological evaluation, if not previously provided, as well as initiating inter-disciplinary rehabilitation treatment and vocational goal setting, for those patients who are failing to make expected progress 6 to 12 weeks after an injury. The Division recognizes that 3 to 10% of all industrially injured patients will not recover within the timelines outlined in this document despite optimal care. Such individuals may require treatments beyond those 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.

13. GUIDELINE RECOMMENDATIONS AND INCLUSION OF MEDICAL EVIDENCE: *All recommendations are based on available evidence and/or consensus judgment.* When possible, guideline recommendations will note the level of evidence supporting the treatment recommendation. It is generally recognized that early reports of a positive treatment effect are frequently weakened or overturned by subsequent research. When interpreting medical evidence statements in the guideline, the following apply:

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

All recommendations in the guideline are considered to represent reasonable care in appropriately selected cases, irrespective of the level of evidence or consensus statement attached to them. Those procedures considered inappropriate, unreasonable, or unnecessary are designated in the guideline as “**not recommended**.”

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

The remainder of this document should be interpreted within the parameters of these

guideline principles that may lead to more optimal medical and functional outcomes for injured workers.

C. DEFINITION OF THORACIC OUTLET SYNDROME

Thoracic Outlet Syndrome (TOS) may be described as a neurovascular disorder affecting the upper extremity which, on rare occasions, is caused by workplace factors, such as jobs that require repetitive activities of the upper extremities with forward head and shoulder postures. It should be emphasized that occupational TOS is a relatively uncommon disorder and other disorders with similar symptomatology need to be ruled out. (These syndromes can be associated with motor vehicle accident trauma, especially while wearing a shoulder strap).

There are three types of thoracic outlet syndrome. The two vascular types, comprised of subclavian vein or artery pathology, are diagnosed with imaging. Neurogenic TOS (described by some literature as true or classic TOS) consists of a chronic lower trunk brachial plexopathy diagnosed by positive electrodiagnostic testing. It is usually unilateral, predominantly affects women, and results in classic electrophysiologic and physical exam findings such as hand atrophy.

Venous TOS (VTOS) is obstruction of the subclavian vein causing arm swelling. It can be with or without thrombosis. In the workplace, VTOS is usually caused by repetitive activities with the arms above shoulder level. Most workers with this condition also present thrombosis of the subclavian vein. Venous TOS is seldom caused by work-related conditions.

Arterial TOS is usually associated with a cervical rib or anomalous first rib. This is regarded primarily as a predisposing factor. Most people with these ribs never develop symptoms. Precipitating factors in patients with cervical or anomalous ribs are trauma such as motor vehicle accidents or other events causing hyperextension neck injuries. Arterial TOS is rarely a work-related condition.

The majority of patients who present with some physical exam findings of TOS do not have vascular or neurogenic TOS. Their symptoms are caused by myofascial dysfunction. The usual physiologic cause includes abnormal posture, scapular dyskinesis, and pectoralis minor shortening. Myofascial dysfunction with TOS symptoms does not qualify as an operative condition (some literature classifies these cases under the older term of non-specific or disputed TOS). A more general, commonly used diagnostic term for myofascial dysfunction with TOS symptoms is thoracic sprain. Treatment should follow recommendations in the active therapy section. Refer to Section F.11. Therapy-Active.

D. 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 TOS complaint are listed below.

1. **HISTORY TAKING AND PHYSICAL EXAMINATION (HX & PE):** are generally accepted, well-established and widely used procedures which establish the basis for diagnosis, and dictate all other 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. Neurogenic TOS will be described separately from vascular TOS, although some general symptoms may occasionally overlap. Vascular TOS usually requires urgent or emergent treatment as described in the surgical section. Over 90% of all TOS cases are neurogenic, 1% arterial and 3-5% venous. Although the cervical rib has been implicated in TOS, less than 1% of the population has a supernumerary rib from the 7th cervical vertebra, and only 10% of this population has symptoms. Treatment for patients with TOS symptoms begins with jobsite alteration and therapy as described in Section F does not require surgical intervention. Neurogenic TOS may require early surgical intervention if there is significant weakness with corresponding Electromyography/Nerve Conduction Velocities (EMG/NCV) changes. The medical records should reasonably document the following:

- a. **History Taking:**

A careful history documenting exacerbating activities and positions which relieve symptoms is essential. Timing of the onset of symptoms is important. TOS has been associated with trauma and motor vehicle accidents. Clavicular fractures can be related. Baseball pitchers may present with TOS symptoms. Avocational pursuits should also be specifically documented. A cervical rib is congenital, and considerations regarding work relatedness should take this into account.

- i. **Symptoms common to neurogenic TOS:**

Neurological symptoms are usually consistent. Other neurologic diagnoses should be considered such as other brachial plexus injuries. Neck pain is often the first symptom with complaints within the first few days of injury. Occipital headaches may also occur early. Some patients experience coldness or color changes in the hands. Neurogenic symptoms include the following:

- A) Forearm (frequently medial), or proximal upper extremity pain including: neck, trapezius, chest, axillar, shoulder and/or arm. Examiner should ask specifically about each area.
- B) Numbness and paresthesia in arm, hand, and fingers:
 - 1) The most common patterns are 4th and 5th digits or all 5 fingers.
 - 2) Symptoms may occur in the 1st, 2nd and 3rd digits, but one must rule out carpal tunnel syndrome.

- C) The most common complaints are upper extremity weakness in the arm and/or hand. Frequently dropping things is a common complaint.
- D) Arm elevation is an exacerbating factor. Common complaints are disturbed sleep, trouble combing hair, putting on clothing, driving a car, or carrying objects with shoulder straps such as back packs.

ii. Symptoms in Venous TOS:

- A) Arm swelling.
- B) Color change – dark red, purple.
- C) Pain is mild. Arm feels tight.
 - Sudden onset of swelling suggests a venous blood clot. This is urgent, but not emergent. Requires treatment within 24 hours. Arm viability is NOT threatened.

iii. Symptoms of Arterial TOS – are due to arterial embolus to arm or hand

- A) Never swollen.
- B) Color change – white, looks ischemic.
- C) Claudication – pain in forearm when using it for any activity.
- D) Pain at rest – suggests ischemia, pregangrene.
- E) Numbness – suggests ischemia, pregangrene.
 - This condition is urgent to emergent. Needs attention within 6-12 hours.

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

Patient-reported outcomes, whether of pain or function, are susceptible to a phenomenon called response shift. This refers to changes in self-evaluation which may accompany changes in health status. Patient self-reports may not coincide with objective measures of outcome, due to reconceptualization of the impact of pain on daily function and internal recalibration of pain scales. Response shift has potential to obscure treatment effects in clinical trials and clinical practice, and may lead to apparent discrepancies in patient-reported outcomes following treatment interventions. While methods of measuring and accounting for response shift are not yet fully developed, understanding that the phenomenon exists can help clinicians understand what is happening when some

measures of patient progress appear inconsistent with other measures of progress.

Questionnaires may also be helpful to describe and follow symptoms and to identify coexisting conditions. Examples include Disability of the Arm, Shoulder and Hand (DASH), the Cervical Brachial Symptom Questionnaire, and depression screening such as the Beck depression scale.

b. **Occupational Relationship for Neurogenic and Vascular TOS:**

In many cases, trauma is the cause of venous and arterial or neurogenic TOS. Clavicular fractures, cervical strain (including whiplash), and other causes of cervical trauma injuries have been associated with TOS. Continual overhead lifting or motion may contribute as can static postures in which the shoulders droop and the head is inclined forward. Activities which cause overdeveloped scalene muscles such as weight-lifting, baseball, rowing and swimming may contribute. The causes of TOS can be placed into 3 general categories: trauma, posture, and repetitive activities.

The Paget-Schroetter syndrome, or effort thrombosis of the subclavian vein, may occur in athletes or workers with repetitive overhead forceful motion and neck extension. It may be caused by microtraumas and by venous stasis induced by mechanical stress on the vein.

Arterial thrombosis or symptoms from subclavian aneurysms or stenosis are usually not related to work or trauma, but are associated with a cervical rib or an anomalous first rib.

Both classic neurogenic TOS (usually due to a cervical or anomalous first rib) and TOS due to arterial compromise from stenosis or aneurysm are rarely work-related conditions.

None of the following anatomical findings are pathognomonic for TOS as they occur frequently in the asymptomatic population also:

- congenital bands and ligaments around the scalene muscles
- a complete or incomplete cervical rib
- interdigitating muscle fibers between the anterior and middle scalene muscles.

c. **Physical Findings:**

Physical examination signs are used to diagnose neurogenic TOS. Both extremities should be examined to compare symptomatic and asymptomatic sides.

i. Provocative maneuvers (listed below) must reproduce the symptoms of TOS to be considered positive.

A) Tenderness over scalene muscles in supraclavicular area.

- B) Pressure in supraclavicular area elicits symptoms in arm/hand, or Tinel's sign over the brachial plexus is positive. The supraclavicular pressure test is positive for paresthesia in approximately 15% of asymptomatic individuals.
- C) Elevated arm stress test (EAST) is performed with the arms abducted and shoulders externally rotated to 90 degrees with elbows bent to 90 degrees for 1 minute. The patient may also be asked to repetitively open and close fists (Roos Test), however, this is not required. A positive test reproduces upper extremity symptoms or dropping of arms to alleviate symptoms within 60 seconds, often within 30 seconds.

Some literature has suggested another provocative elevated arm stress test, Wright's test. The patient holds his arms over head for one minute with elbows extended, wrists in a neutral position, and forearm midway between supination and pronation. If symptoms are reproduced, the test is positive.

- D) Upper Limb Tension Test (ULTT). This test is comparable to straight leg raising in the lower extremity. It is a modification of Elvey's test first described in about 1990. There are 3 steps, or positions:

- 1) Arm is extended 90° with elbow straight out.
- 2) Wrist is dorsi-flexed.
- 3) Head is tilted to opposite side, putting ear to shoulder (contralateral side).

A positive response is onset of paresthesia in the hand or pain down the arm. This test is not specific for neurogenic TOS and may be positive in other upper extremity neurogenic conditions.

ii. Posture related brachial tests (listed below) must reproduce the symptoms of TOS to be considered positive.

- A) Head tilting: lateral flexion of the neck (ear to shoulder) causes radiating pain and paresthesia in the contralateral arm consistent with TOS.
- B) Neck Rotation or Adson's: Turn the chin all the way to the side and move opposite arm into extension, abduction and then external rotation. A positive response is the onset of pain and/or paresthesia on the opposite (contralateral) side.

iii. Neurological examination:

- A) Sensory exam: may show decreased sensation to light touch, pain, vibration, and/or temperature in lower brachial plexus distribution. The entire ring finger is frequently involved. The entire little finger and lateral side of the ring finger may show sensory changes and occasionally the long finger showed

sensory changes. This contrasts with ulnar neuropathy, which usually involves only the ulnar side of the ring finger.

- B) Motor exam: weakness and/or muscle atrophy in either upper or lower trunk distributions including, but not limited to, valid dynamometer readings indicative of relative weakness in the affected limb compared to the unaffected limb. In lower plexus injuries, the abductor pollicis brevis often demonstrates more involvement and atrophy than the intrinsic interosseous muscles. Atrophy of the thenar eminence as compared to the asymptomatic hand can occasionally be observed.

iv. Physical exam findings for venous and arterial TOS cases:

Suspicion of vascular compromise should lead to confirmation using appropriate imaging procedures.

- A) Arterial cases usually demonstrate an absent radial pulse at rest, a pale hand, and often ischemic fingers.
- B) Venous obstruction presents with visible or distended superficial veins on the affected side involving the anterior axillary fold and chest wall. The arm is usually swollen and cyanotic. Measurement of the circumference of wrist and upper arm/biceps may objectively demonstrate asymmetry.

v. Physical Exam - other tests which are recommended and may indicate additional diagnostic considerations.

- A) Neck rotation may be restricted and can indicate the presence of additional pathology.
- B) Rotator cuff/acromioclavicular (AC) joint tenderness suggests rotator cuff, biceps tendonitis, or AC joint disease.
- C) Trapezius muscle, shoulder girdle muscles or paraspinal muscle tenderness suggests a myofascial component or protective spasm. Trapezius tenderness is common in both neurogenic TOS and pectoralis minor syndrome.
- D) Drooping shoulders secondary to nerve injuries can be present with TOS symptoms. If a spinal accessory, long thoracic or other nerve injury is identified, treatment should focus on therapy for the nerve injury in addition to conservative measures for TOS. Refer to the Shoulder Injury Medical Treatment Guidelines, Section E.4. Brachial Plexus and Shoulder Nerve Injuries.
- E) The following tests suggest carpal tunnel syndrome: carpal tunnel compression test, flicking the wrist secondary to paresthesia, Tinel's sign and/or Phalen's sign.
- F) Positive Tinel's sign at elbow (over ulnar groove) suggests ulnar nerve entrapment.

- G) Positive Tinel's sign over the pronator teres muscle suggests median nerve involvement. Positive Tinel's sign over the radial tunnel suggests radial nerve compression.

- d. Cervical Spine X-ray:** is a generally accepted, well-established procedure indicated to rule out cervical spine disease, fracture, cervical rib, or rudimentary first rib when clinical findings suggest these diagnoses. Cervical spine x-rays should also be considered when there is an asymmetric diminished pulse in an arm that is symptomatic. X-rays are most useful when arterial TOS is suspected. The presence of a cervical rib does not confirm the diagnosis unless other clinical signs and symptoms are present, as many cervical ribs are asymptomatic. Therefore, routine roentgenographic evaluation of the cervical spine is frequently unnecessary early in the course of treatment for patients with thoracic outlet symptoms due to myofascial dysfunction.
- e. Vascular Studies:** Vascular laboratory studies, including duplex scanning, Doppler studies, standard and MR arteriography and venography are required for patients presenting with arterial or venous occlusion, as these patients may require immediate thrombolytic intervention. These studies are not indicated for neurogenic TOS.

E. FOLLOW-UP DIAGNOSTIC IMAGING AND TESTING PROCEDURES

One diagnostic imaging procedure may provide the same or distinctive information as 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 diagnostic imaging procedures have a significant percentage of specificity and sensitivity for various diagnoses. None is specifically characteristic of a certain diagnosis. Clinical information obtained by history taking and physical examination should form the basis for selecting an imaging procedure and interpreting its results.

Practitioners should be aware of the radiation doses associated with various procedures and provide appropriate warnings to patients. Coloradans have a background exposure to radiation, and unnecessary CT scans or X-rays increase the lifetime risk of cancer death.

When a diagnostic procedure, in conjunction with clinical information, can provide sufficient information to establish an accurate diagnosis, the second diagnostic procedure will become a redundant procedure. At the same time, a subsequent diagnostic procedure can be a complementary diagnostic procedure if the first or preceding procedures, in conjunction with clinical information, cannot provide an accurate diagnosis. Usually, preference of a procedure over others depends upon availability, a patient's tolerance, and/or the treating practitioner's familiarity with the procedure.

1. CERVICAL COMPUTED AXIAL TOMOGRAPHY OR MAGNETIC RESONANCE

IMAGING (CT/MRI): are generally accepted, well-established procedures indicated to rule out cervical disc or other cervical spine disorders when clinical findings suggest these diagnoses. It should not be routinely performed for TOS. MRI is the preferred test over a CT unless a fracture is suspected, and then CT may be superior to MRI. CT/MRI is not indicated early unless there is a neurological deficit and/or the need to rule out a space-occupying lesion, such as a tumor. A number of anatomic variants which may be identified are not necessarily pathognomonic for TOS. Refer to Section D.1.b. Occupational Relationship for Neurogenic and Venous and Arterial TOS. Repeat cervical MRI is not indicated for TOS. If cervical spine injury is confirmed, refer to Division's Cervical Spine Injury Medical Treatment Guidelines. If a cervical spine disorder is not suspected, conservative therapy as indicated in Section F. Non-operative Procedures should be done for at least 8 to 12 weeks, prior to ordering an MRI for persistent symptoms.

2. ELECTRODIAGNOSTIC STUDIES:

a. Electromyography/Nerve Conduction Velocities (EMG/NCV): are generally accepted, well-established procedure. EMG/NCV is primarily indicated to rule out other nerve entrapment syndromes such as cervical nerve roots, ulnar neuropathy, carpal tunnel or cubital tunnel syndrome when indicated by clinical examination, or to establish neurogenic TOS. Most cases of myofascial dysfunction with thoracic outlet symptoms have normal electrodiagnostic studies, but EMG/NCV should be considered when symptoms have been present for approximately 3 months or if the patient has failed 8 weeks of conservative therapy. EMG/NCV may also be performed to rule out other disorders. F wave measurements have no utility in the work up for TOS. Nerve conduction studies across the thoracic outlet are considered controversial for diagnostic purposes by some authors.

The diagnosis should be made by comparison to the normal extremity. For bilateral disease, each EMG lab must establish its own absolute limits of latency and amplitude from volunteer controls, so that measurements exceeding these limits can be noted. The EMG and NCV study is an extension of the physical exam. Thus, an electrical diagnosis cannot be made without clinical correlation.

Criteria for Neurogenic TOS:

- i. Reduction of the ulnar sensory nerve action potential to digits (usually less than 60% of unaffected side); or
- ii. Medial antebrachial cutaneous nerve sensory action potential which is low or absent compared to the unaffected side; or
- iii. Reduction of the median M-wave amplitude (usually less than 50% of unaffected side); or
- iv. Needle EMG examination reveals neurogenic changes in intrinsic hand muscles and the abductor pollicis brevis muscle; or
- v. Abnormal nerve conduction of one of the following: medial antebrachial cutaneous (MAC) nerve amplitude retro between sides of 2 or more, amplitude under 10 mV, latency difference of between sides of 0.3 or more, or latency more than 2.4 msec; or
- vi. A C8 stimulation study may be done when there are equivocal findings from the above tests, i through v. A positive test would demonstrate slowed velocity.

Related Studies:

There is some evidence that a latency in the MAC nerve greater than or equal to 2.4 ms and an amplitude less than 10 microvolts may confirm a clinical diagnosis of neurogenic TOS, but need not be a required part of the diagnostic evaluation. There is inadequate evidence that it is a robust diagnostic test for neurogenic TOS, since in this study the clinical examination was used to select patients for surgery even if electrodiagnostic testing is optional.

One study concluded that comparison of the amplitude of sensory nerve action potential of MAC on the injured or non-injured side was comparatively helpful for the diagnosis of TOS; however, the latency difference between the medial antebrachial cutaneous nerve and the ulnar nerve did not differ significantly between the TOS side and the asymptomatic side.

- b. **Portable Automated Electrodiagnostic Device:** (also known as SurfaceEMG) is not a substitute for conventional EMG/NCV testing in clinical decision making, and therefore, is **not recommended**.
- c. **Quantitative Sensory Testing (QST):** Research is not currently available on the use of QST in the evaluation of TOS. QST tests the entire spectrum of the neurological system including the brain. It is not able to reliably distinguish between organic and psychogenic pathology and therefore, is **not recommended**.

- 3. VASCULAR STUDIES:** Noninvasive vascular testing, such as pulse-volume recording in different positions, is not indicated in cases of neurogenic TOS. Since the presence or absence of a pulse cutoff on physical examination is not helpful in establishing a diagnosis of TOS, the recording of finer degrees of positional pulse alteration will not add to the diagnosis. Vascular laboratory studies, including duplex scanning, Doppler studies, standard and MR arteriography and venography, are not cost-effective in cases of neurogenic TOS. These studies are only indicated in patients who have arterial or venous occlusive signs. Dynamic venography with the arm in 180 degrees of abduction may be used in cases with continued swelling and/or periodic cyanosis who have not improved with conservative therapy. Approximately 20% of asymptomatic individuals will have an abnormal dynamic venogram. Some individuals may have a pectoralis minor syndrome which occludes the axillary vein rather than the subclavian vein. In these cases, less invasive surgery than the TOS operative procedures may be indicated.
- 4. THERMOGRAPHY:** is not generally accepted or widely used for TOS. It may be used if the differential diagnosis includes CRPS; in such cases, refer to the Division's Complex Regional Pain Syndrome/Reflex Sympathetic Dystrophy Medical Treatment Guidelines.
- 5. ANTERIOR SCALENE OR PECTORALIS MUSCLE BLOCKS:** may be performed to provide additional information prior to expected surgical intervention. It is recommended that EMG or sonography guidance be used to assure localization. Patients who have work-related cumulative trauma are likely to have less pain relief than those with specific injuries. A recent review of multiple TOS surgical articles found that comorbidities were better predictors of long-term improvement in quality of life than pre-operative positive scalene blocks.
- 6. BOTULINUM INJECTIONS:** There is some evidence that botulinum toxin type A in a dose of 75U injected into the scalene muscles does not differ appreciably from an injection of placebo in patients with TOS of several years' duration. Complications include dysphagia and dysphonia. Thus, it is ***not recommended*** for diagnosis.
- 7. PERSONALITY/PSYCHOLOGICAL/PSYCHOSOCIAL EVALUATIONS:** are generally accepted and well-established diagnostic procedures with selective use in the acute TOS population and more widespread use in the sub-acute and chronic TOS population.

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

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

- a. Employment history;
- b. Interpersonal relationships — both social and work;
- c. Leisure activities;
- d. Current perception of the medical system;

- e. Results of current treatment;
- f. Perceived locus of control; and
- g. Childhood history, including abuse and family history of disability.

This information should provide clinicians with a better understanding of the patient, and enable a more effective rehabilitation.

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

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

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

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

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

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

There is some evidence that an FCE fails to predict which injured workers with chronic low back pain will have sustained return to work. Another cohort study

concluded that there was a significant relation between FCE information and return to work, but the predictive efficiency was poor. There is some evidence that time off work and gender are important predictors for return to work. Floor-to-waist lifting may also help predict return to work, however, the strength of that relationship has not been determined.

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

Full FCEs are rarely necessary. In many cases, a work tolerance screening or return to work performance will identify the ability to perform the necessary job tasks. There is some evidence that a short form FCE reduced to a few tests produces a similar predictive quality compared to the longer 2-day version of the FCE regarding length of disability and recurrence of a claim after return to work.

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

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

c. Jobsite Evaluation: is a comprehensive analysis of the physical, mental and sensory components of a specific job. These components may include, but are not limited to: (a) postural tolerance (static and dynamic); (b) aerobic requirements; (c) range of motion; (d) torque/force; (e) lifting/carrying; (f) cognitive demands; (g) social interactions; (h) visual perceptual; (i) sensation; (j) coordination; (k) environmental requirements; (l) repetitiveness; and (m) essential job functions. Job descriptions provided by the employer are helpful but should not be used as a substitute for direct observation.

A jobsite evaluation may include observation and instruction of how work is done, what material changes (desk, chair) should be made, and determination of readiness to return to work. Postural risk factors should be identified and awkward postures of overhead reach, hyperextension or rotation of the neck, shoulder drooped or forward-flexed and head-chin forward postures should be eliminated. Unless combined with one of the above postures, repetitiveness is not by itself a risk factor. Refer to Cumulative Trauma Disorder and Shoulder Guidelines for further suggestions.

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

- i. To determine if there are potential contributing factors to the person's condition and/or for the physician to assess causality;
 - ii. To make recommendations for, and to assess the potential for ergonomic changes;
 - iii. To provide a detailed description of the physical and cognitive job requirements;
 - iv. To assist the patient in their return to work by educating them on how they may be able to do their job more safely in a bio-mechanically appropriate manner;
 - v. To give detailed work/activity restrictions.
- ❖ Frequency: One time with additional visits as needed for follow-up per jobsite.

- d. **Vocational Assessment:** If the injury is such that the practitioner can easily determine that the worker will be unable to return to his/her previous occupation, then vocational rehabilitation assistance at that time may aid in the overall medical management and rehabilitation of the patient. The physician may decide that the patient is unable to return to the previous occupation prior to declaration of MMI.

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

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

- e. **Work Tolerance Screening:** is a determination of an individual's tolerance for performing a specific job based on a job activity or task and may be used when a full Functional Capacity Evaluation is not indicated. The screening is monitored by a therapist and may include a test or procedure to specifically identify and quantify work relevant cardiovascular, physical fitness and postural tolerance. It may also address ergonomic issues affecting the patient's return-to-work potential.

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

F. THERAPEUTIC PROCEDURES – NON-OPERATIVE

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

First, patients undergoing therapeutic procedure(s) should be released or returned to modified or restricted duty during their rehabilitation at the earliest appropriate time. Refer to Section F.10. Return to Work for detailed information.

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

Third, providers should provide and document patient education. Before diagnostic tests or referrals for invasive treatment take place, the patient should be able to clearly articulate the goals of the intervention, the general side effects and associated risks, and the patient's agreement with the expected treatment plan. Sleep positions should be addressed to avoid abduction, overhead posture or pressure.

Last, formal psychological or psychosocial evaluation should be performed on patients not making expected progress within 6 to 12 weeks following injury and whose subjective symptoms do not correlate with objective signs and tests.

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

The following procedures are listed in alphabetical order.

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

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

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

Clinical trials of acupuncture typically enroll participants who are interested in acupuncture, and who may respond to some of the non-specific aspects of the intervention more than would be expected of patients who have no interest in or desire for acupuncture. The non-specific effects of acupuncture may not be produced in patients who have no wish to be referred for it.

Another study provides good evidence that true acupuncture at traditional medians is marginally better than sham acupuncture with blunt needles in reducing pain, but effects on disability are unclear. In these studies 5–15 treatments were provided. Comparisons of acupuncture and sham acupuncture have been inconsistent, and the advantage of true over sham acupuncture has been small in relation to the advantage of sham over no acupuncture.

Acupuncture is recommended for subacute or chronic pain patients who are trying to increase function and/or decrease medication usage and have an expressed interest in this modality. It is also recommended for subacute or acute pain for patients who cannot tolerate nonsteroidal anti-inflammatory drugs (NSAIDs) or other medications. Acupuncture is not the same procedure as dry needling for coding purposes; however, some acupuncturists may use acupuncture treatment for myofascial trigger points. Dry needling is performed specifically on myofascial trigger points. Refer to Section F.3.c. Trigger Point Injections and Dry Needling Treatment.

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

- a. 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.

- b. 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.

- c. 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.

- ❖ Time to Produce Effect: 3 to 6 treatments.
- ❖ Frequency: 1 to 3 times per week.
- ❖ Optimum Duration: 1 to 2 months.
- ❖ Maximum Duration: 15 treatments.

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

- d. Other Acupuncture Modalities:** Acupuncture treatment is based on individual patient needs and therefore treatment may include a combination of procedures to enhance treatment effect. Other procedures may include the use of heat, soft tissue manipulation/massage, and exercise. Refer to Sections F.11. Therapy- Active (Therapeutic Exercise) and F.12. Therapy- Passive (Massage and Superficial Heat and Cold Therapy) for a description of these adjunctive acupuncture modalities and time frames.

- 2. BIOFEEDBACK:** Biofeedback is a form of behavioral medicine that helps patients learn self-awareness and self-regulation skills for the purpose of gaining greater control of their physiology, such as muscle activity, brain waves, and measures of autonomic nervous system activity. Stress-related psycho-physiological reactions may arise as a reaction to organic pain and, in some cases, may cause pain. Electronic instrumentation is used to monitor the targeted physiology and then displayed or fed back to the patient visually, auditorily, or tactilely, with coaching by a biofeedback specialist. There is good evidence that biofeedback or relaxation therapy is equal in effect to cognitive behavioral therapy for chronic low back pain.

Indications for biofeedback include cases of musculoskeletal injury, in which muscle

dysfunction or other physiological indicators of excessive or prolonged stress response affects and/or delays recovery. Other applications include training to improve self-management of pain, anxiety, panic, anger or emotional distress, opioid withdrawal, insomnia/sleep disturbance, and other central and autonomic nervous system imbalances. Biofeedback is often utilized for relaxation training. Mental health professionals may also utilize it as a component of psychotherapy, where biofeedback and other behavioral techniques are integrated with psychotherapeutic interventions. Biofeedback is often used in conjunction with physical therapy or medical treatment.

Recognized types of biofeedback include the following:

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

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

Psychologists or psychiatrists who provide psycho-physiological therapy, which integrates biofeedback with psychotherapy, should be either Biofeedback Certification International Alliance (BCIA) certified or practicing within the scope of their training. All non-licensed health care providers of biofeedback for chronic pain patients must be BCIA certified and shall have their biofeedback treatment plan approved by the authorized

treating psychologist or psychiatrist. Biofeedback treatment must be done in conjunction with the patient's psychosocial intervention. Biofeedback may also be provided by health care providers who follow a set treatment and educational protocol. Such treatment may utilize standardized material or relaxation tapes.

- ❖ Time to Produce Effect: 3 to 4 sessions.
- ❖ Frequency: 1 to 2 times per week.
- ❖ Optimum Duration: 6 to 8 sessions.
- ❖ Maximum Duration: 10 to 12 sessions. Treatment beyond 12 sessions must be documented with respect to need, expectation, and ability to facilitate positive symptomatic and functional gains.

3. INJECTIONS - THERAPEUTIC:

a. Scalene Blocks: have no therapeutic role in the treatment of TOS.

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

There is some evidence that botulinum toxin type A in a dose of 75U injected into the scalene muscles does not differ appreciably from an injection of placebo in patients with TOS of several years' duration. Therefore, it is ***not recommended***. In addition, because muscle paralysis from the injection can lead to muscle atrophy and other unexpected pathology over time, botulinum toxin is ***not recommended***.

c. Trigger Point Injections and Dry Needling Treatment:

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

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

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

- ii. 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 active therapy programs. Trigger point injections should be utilized primarily for the purpose of facilitating functional progress. Patients should continue in an aggressive aerobic and stretching therapeutic exercise program as tolerated throughout the time period they are undergoing intensive myofascial interventions. Myofascial pain is often associated with other underlying structural problems and any abnormalities need to be ruled out prior to injection.

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

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

- ❖ Time to produce effect: Local anesthetic 30 minutes; 24 to 48 hours for no anesthesia.
- ❖ Frequency: Weekly. Suggest no more than 4 injection sites per session per week to avoid significant post-injection soreness.
- ❖ Optimum duration: 4 Weeks total for all injection sites.
- ❖ Maximum duration: 8 weeks total for all injection sites. Occasionally, patients may require 2 to 4 repetitions of trigger point injection series over a 1 to 2 year period.

4. INTERDISCIPLINARY REHABILITATION PROGRAMS: This is the gold standard of treatment for individuals who have not responded to less intensive modes of treatment.

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

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

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

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

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

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

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

- Communication: To ensure positive functional outcomes, communication between the patient, insurer, and all professionals involved must be coordinated

and consistent. Any exchange of information must be provided to all professionals, including the patient. Care decisions should be communicated to all and should include the family and/or support system.

- Documentation: Through documentation by all professionals involved and/or discussions with the patient, it should be clear that functional goals are being actively pursued and measured on a regular basis to determine their achievement or need for modification.
- Treatment Modalities: Use of modalities may be necessary early in the process to facilitate compliance with and tolerance to therapeutic exercise, physical conditioning, and increasing functional activities. Active treatments should be emphasized over passive treatments. Active and self-monitored passive treatments should encourage self-coping skills and management of pain, which can be continued independently at home or at work. Treatments that can foster a sense of dependency by the patient on the caregiver should be avoided. Treatment length should be decided based upon observed functional improvement. For a complete list of active and passive therapies, refer to Section F.11. Therapy – Active and F.12. Therapy – Passive. All treatment timeframes may be extended based on the patient's positive functional improvement.
- Therapeutic Exercise Programs: A therapeutic exercise program should be initiated at the start of any treatment rehabilitation. Such programs should emphasize education, independence, and the importance of an on-going exercise regimen. There is good evidence that exercise alone or part of a multi-disciplinary program results in decreased disability for workers with non-acute low back pain. There is not sufficient evidence to support the recommendation of any particular exercise regimen.
- Return to Work: The authorized treating physician should continually evaluate the patient for their potential to return to work. For patients currently employed, efforts should be aimed at keeping them employed. Formal rehabilitation programs should provide assistance in creating work profiles. For more specific information regarding return to work, refer to Section F.10. Return to Work.
- Patient Education: Patients with pain need to re-establish a healthy balance in lifestyle. All providers should educate patients on how to overcome barriers to resuming daily activity, including pain management, decreased energy levels, financial constraints, decreased physical ability, and change in family dynamics.
- Psychosocial Evaluation and Treatment: Psychosocial evaluation should be initiated, if not previously done. Providers of care should have a thorough understanding of the patient's personality profile, especially if dependency issues are involved. Psychosocial treatment may enhance the patient's ability to participate in pain treatment rehabilitation, manage stress, and increase their problem-solving and self-management skills.
- Vocational Assistance: Vocational assistance can define future employment opportunities or assist patients in obtaining future employment. Refer to Section F.10. Return to Work for detailed information.

Interdisciplinary programs are characterized by a variety of disciplines that participate in the assessment, planning, and/or implementation of the treatment program. These programs are for patients with greater levels of perceived disability, dysfunction, de-

conditioning, and psychological involvement. Programs should have sufficient personnel to work with the individual in the following areas: behavioral, functional, medical, cognitive, pain management, psychological, social, and vocational.

a. Formal Interdisciplinary Rehabilitation Programs:

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

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

The Medical Director of the pain program should ideally be board certified in pain management; or he/she should be board certified in his/her specialty area and have completed a one-year fellowship in interdisciplinary pain medicine or palliative care recognized by a national board or have two years of experience in an interdisciplinary pain rehabilitation program. Teams that assist in the accomplishment of functional, physical, psychological, social, and vocational goals must include: a medical director, pain team physician(s), and a pain team psychologist. Professionals from other disciplines on the team may include, but are not limited to: a biofeedback therapist, an occupational therapist, a physical therapist, a registered nurse (RN), a case manager, an exercise physiologist, a psychologist, a psychiatrist, and/or a nutritionist.

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

- ii. Occupational Rehabilitation: This is a formal interdisciplinary program addressing a patient's employability and return to work. It includes a

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

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

The occupational medicine rehabilitation interdisciplinary team should, at a minimum, be comprised of a qualified medical director who is board certified with documented training in occupational rehabilitation; team physicians having experience in occupational rehabilitation; an occupational therapist; and a physical therapist.

As appropriate, the team may also include any of the following: chiropractor, an RN, a case manager, a psychologist, a vocational specialist, or a certified biofeedback therapist.

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

iii. Opioid/Chemical Treatment Programs: Refer to the Division's Chronic Pain Disorder Medical Treatment Guidelines.

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

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

Patients should be referred to professionals experienced in outpatient treatment of chronic pain. The Division recommends the authorized treating physician consult with physicians experienced in the treatment of chronic pain to develop

the plan of care. Communication among care providers regarding clear objective goals and progress toward the goals is essential. Employers should be involved in return to work and work restrictions, and the family and/or social support system should be included in the treatment plan. Professionals from other disciplines likely to be involved include: a biofeedback therapist, an occupational therapist, a physical therapist, an RN, a psychologist, a case manager, an exercise physiologist, a psychiatrist, and/or a nutritionist.

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

5. MEDICATIONS:

Thrombolytic agents will be required for some vascular TOS conditions.

Medication use is appropriate for pain control in TOS. 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.

Acetaminophen is an effective and safe initial analgesic. Nonsteroidal anti-inflammatory drugs (NSAIDs) are useful in the treatment of inflammation, and for pain control. Pain is subjective in nature and should be evaluated using a scale to rate effectiveness of the analgesic in terms of functional gain. Other medications, including antidepressants and anti-convulsants, may be useful in selected patients with neuropathic and/or chronic pain (Refer to the Division's Chronic Pain Medical Treatment Guidelines). Opioids are rarely indicated for treatment of TOS, and they should be primarily reserved for the treatment of acute severe pain for a limited time on a case-by-case basis. Topical agents may be beneficial in the management of localized upper extremity pain.

The use of a patient completed pain drawing, visual analog scale (VAS), is highly recommended to help providers track progress. Functional objective goals should be monitored regularly to determine the effectiveness of treatment. The patient should be advised regarding the interaction with prescription and over-the-counter herbal products.

The following medications are listed in alphabetical order:

- a. Acetaminophen:** An effective analgesic with anti-pyretic but not anti-inflammatory activity. Acetaminophen is generally well-tolerated, causes little or no gastrointestinal (GI) irritation, and is not associated with ulcer formation. Acetaminophen has been associated with liver toxicity in overdose situations or in chronic alcohol use. Patients may not realize that many over-the-counter preparations contain acetaminophen. The total daily dose of acetaminophen is

recommended not to exceed three grams per 24-hour period, from all sources, including narcotic-acetaminophen combination preparations.

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

b. Anticonvulsants: Although the mechanism of action of anticonvulsant drugs in neuropathic pain states remains to be fully defined, some appear to act as nonselective sodium channel blocking agents. A large variety of sodium channels are present in nervous tissue. Some of these channels are important mediators of nociception, as they are found primarily in unmyelinated fibers and their density increases following a nerve injury. While the pharmacodynamic effects of the various anticonvulsant drugs are similar, the pharmacokinetic effects differ significantly. Gabapentin and pre-gabapentin, by contrast, is a relatively non-significant enzyme inducer, creating fewer drug interactions. Because anticonvulsant drugs may have more problematic side-effect profiles, their use should usually be deferred until tricyclic-related medications have failed to relieve pain. All patients on these medications should be monitored for suicidal ideation.

Carbamazepine has important effects as an inducer of hepatic enzymes and may influence the metabolism of other drugs enough to present problems in patients taking interacting drugs. There is some evidence that oxcarbazepine (Trileptal) may be effective for neuropathic pain, but dose escalation must be done carefully, since there is good evidence that rapid dose titration produces side-effects greater than the analgesic benefits. Carbamazepine is **generally not recommended**.

There is an association between older anticonvulsants including gabapentin and non-traumatic fractures for patients older than 50, which should be taken into account when prescribing these medications.

i. Gabapentin

- A) Description – Structurally related to gamma-aminobutyric acid (GABA) but does not interact with GABA receptors.
- B) Indications – As of the time of this guideline writing, formulations of gabapentin have been FDA approved for post-herpetic neuralgia and partial seizures.

There is some evidence that gabapentin may benefit some patients with post-traumatic neuropathic pain. There is good evidence that gabapentin is not superior to amitriptyline. There is some evidence that nortriptyline and gabapentin are equally effective for pain relief of post herpetic neuralgia. There is some evidence that gabapentin given with morphine may result in lower side effects from morphine and produces greater analgesia at lower doses than those usually required for either medication alone. There is strong evidence that gabapentin is more effective than placebo for neuropathic pain, even though it provides complete pain relief to a minority of patients. There is some

evidence that a combination of gabapentin and nortriptyline provides more effective pain relief than monotherapy with either drug. Given the cost of gabapentin, it is recommended that patients who are medically appropriate receive a trial of tricyclics before use of gabapentin.

- C) Relative Contraindications – Renal insufficiency. Dosage may be adjusted to accommodate renal dysfunction.
- D) Dosing and Time to Therapeutic Effect – Dosage should be initiated at a low dose in order to avoid somnolence and may require 4 to 8 weeks for titration. Dosage should be adjusted individually.
- E) Major Side Effects – Sedation, confusion, dizziness, peripheral edema. Patients should also be monitored for suicidal ideation and drug abuse.
- F) Drug Interactions – antacids.
- G) Laboratory Monitoring – Renal function.

ii. Pregabalin

- A) Description – Structurally related to gamma-aminobutyric acid (GABA) but does not interact with GABA receptors.
- B) Indications –As of the time of this guideline writing, formulations of pregabalin have been FDA approved for neuropathic pain associated with diabetic peripheral neuropathy, post-herpetic neuralgia, and fibromyalgia. It may also be an adjunctive therapy for partial-onset seizures.

There is strong evidence that pregabalin has a substantive benefit for a minority, about 25%, of neuropathic pain patients, most of whom report between 30 and 50% relief of symptoms. Given the cost of pregabalin and its response for a minority of patients, it is recommended that patients who are medically appropriate receive a trial of amitriptyline or another first-line agent before use of pregabalin.

- C) Contraindications – allergy to medication, prior history of angioedema. Renal insufficiency is a relative contraindication, requiring a modified dose.
- D) Dosing and Time to Therapeutic Effect – Dosage may be increased over several days and doses above 150 mg are usually required. The full benefit may not be achieved for 6 to 8 weeks.
- E) Major Side Effects – Dizziness, confusion, sedation, dry mouth, weight gain, and visual changes have been reported. Patients should also be monitored for suicidal ideation and drug abuse.

Congestive heart failure may be exacerbated in some patients. Decreased platelets have been reported.

- F) Drug Interactions – Opioids, benzodiazepines, and alcohol.
- G) Laboratory Monitoring – Renal function, and platelets, and creatinine kinase as appropriate for individual cases.

iii. Topiramate

- A) Description – Sulfamate substitute monosacchride.
- B) Indications – FDA approved for partial seizures or prophylaxis for migraines. There is good evidence that topiramate demonstrates minimal effect on chronic lumbar radiculopathy or other neuropathic pain. Therefore it is **generally not recommended** for chronic pain with the exception of chronic, functionally impairing headache. If it is utilized, this would be done as a third or fourth line medication in appropriate patients.

iv. Lamotrigine – This anti-convulsant drug is not FDA approved for use with neuropathic pain. Due to reported deaths from toxic epidermal necrolysis and Stevens-Johnson syndrome, increased suicide risk, and incidents of aseptic meningitis, it is used with caution for patients with seizure or mood disorders. There is good evidence that lamotrigine is not effective for neuropathic pain and that the potential harms are likely to outweigh the benefits, therefore it is **not recommended** for most patients.

c. **Antidepressants:** are classified into a number of categories based on their chemical structure and their effects on neurotransmitter systems. Their effects on depression are attributed to their actions on disposition of norepinephrine and serotonin at the level of the synapse. Although these synaptic actions are immediate, the symptomatic response in depression is delayed by several weeks. When used for chronic pain, the effects may in part arise from treatment of underlying depression, but may also involve additional neuromodulatory effects on endogenous opioid systems, raising pain thresholds at the level of the spinal cord.

Pain responses may occur at lower drug doses with shorter times to symptomatic response than are observed when the same compounds are used in the treatment of mood disorders. Neuropathic pain, diabetic neuropathy, post-herpetic neuralgia, and cancer-related pain may respond to antidepressant doses low enough to avoid adverse effects that often complicate the treatment of depression. First line drugs for neuropathic pain are the tricyclics with the newer formulations having better side effect profiles. Serotonin Norepinephrine Reuptake Inhibitors (SNRIs) are considered second line drugs due to their costs and the number needed to treat for a response. Selective serotonin reuptake inhibitors (SSRIs) are used generally for depression rather than neuropathic pain and should not be combined with moderate to high-dose tricyclics.

All patients being considered for anti-depressant therapy should be evaluated and continually monitored for suicidal ideation and mood swings.

i. Tricyclics and older agents.

(e.g., amitriptyline, nortriptyline, doxepin.

- A) Description – Serotonergics, typically tricyclic antidepressants (TCAs), are utilized for their serotonergic properties as increasing Central Nervous System (CNS) serotonergic tone can help decrease pain perception in non-antidepressant dosages. Amitriptyline is known for its ability to repair Stage 4 sleep architecture, a frequent problem found in chronic pain patients and to treat depression, frequently associated with chronic pain. However, higher doses may produce more cholinergic side effects than newer tricyclics such as nortriptyline and desipramine. Doxepin and trimipramine also have sedative effects.
- B) Indications – Some formulations are FDA approved for depression and anxiety. For the purposes of this guideline, they are recommended for neuropathic pain and insomnia. They are **not recommended** as a drug treatment for depression. There is good evidence that gabapentin is not superior to amitriptyline. Given the cost of gabapentin, it is recommended that patients who are medically appropriate to undergo a trial of lower cost tricyclic before use of gabapentin.
- C) Major Contraindications – Cardiac disease or dysrhythmia, glaucoma, prostatic hypertrophy, seizures, high suicide risk, uncontrolled hypertension and orthostatic hypotension. A screening cardiogram may be done for those 40 or older, especially if higher doses are used.
- D) Dosing and Time to Therapeutic Effect – Varies by specific tricyclic. Low dosages, less than 100 mg are commonly used for chronic pain and/or insomnia. Lower doses decrease side effects and cardiovascular risks.
- E) Major Side Effects – Side effects vary according to the medication used; however, the side effect profile for all of these medications is generally higher in all areas except GI distress, which is more common among the SSRIs and SNRIs. Anticholinergic side effects include, but not limited to, dry mouth, sedation, orthostatic hypotension, cardiac arrhythmia, urinary retention, and weight gain. Patients should also be monitored for suicidal ideation and drug abuse.
- F) Drug Interactions – Tramadol (may cause seizures, both also increase serotonin/norepinephrine, so serotonin syndrome is a concern), clonidine, cimetidine, sympathomimetics, valproic acid, warfarin, carbamazepine, bupropion, anticholinergics, quinolones.
- G) Recommended Laboratory Monitoring – Renal and hepatic function. Electrocardiogram (EKG) for those on high dosages, or with cardiac risk.

ii. Selective serotonin reuptake inhibitors (SSRIs) (e.g., citalopram, fluoxetine, paroxetine, sertraline) are **not recommended** for neuropathic pain. They may be used for depression.

iii. Selective Serotonin Nor-epinephrine Reuptake Inhibitor (SSNRI)/Serotonin Nor-epinephrine Reuptake Inhibitors (SNRI).

A) Description – Venlafaxine, duloxetine, and milnacipran.

B) Indications – At the time of this guideline writing, duloxetine has been FDA approved for treatment of diabetic neuropathic pain and chronic musculoskeletal pain. There is good evidence that it is superior to placebo for neuropathic pain at doses of 60mg or 120mg. There is some evidence that it is comparable to pregabalin and gabapentin.

As of the time of this guideline writing, formulations of venlafaxine hydrochloride have been FDA approved for generalized anxiety disorder. There is some evidence it is modestly effective in diabetic neuropathic pain at doses of 150 to 225 mg. There is no evidence of superiority over tricyclics.

As of the time of this guideline writing, formulations of milnacipran have been FDA approved for treatment of fibromyalgia and has a success rate similar to imipramine. It is **not recommended** in patients as a first or second line treatment and is reserved for patients who fail other regimes due to side effects.

C) Relative Contraindications – Seizures, eating disorders.

D) Major Side Effects - Depends on the drug, but commonly includes dry mouth, nausea, fatigue, constipation, and abnormal bleeding. Serotonin syndrome is also a risk. GI distress, drowsiness, and sexual dysfunction are less frequent than other classes. Hypertension and glaucoma. Cardiac issues with venlafaxine and withdrawal symptoms unless tapered. Studies show increased suicidal ideation and attempts in adolescents and young adults. Patients should also be monitored for suicidal ideation and drug abuse.

E) Drug Interactions – Drug specific.

F) Laboratory Monitoring – Drug specific. Hepatic and renal monitoring, venlafaxine may cause cholesterol or triglyceride increases.

iv. Atypical Antidepressants/Other Agents. May be used for depression; however, are not appropriate for neuropathic pain.

d. **Muscle Relaxants:** Appropriate for objective findings of muscle spasm with pain. When prescribing these agents, physicians must seriously consider all CNS side effects including drowsiness or dizziness and the fact that benzodiazepines may be habit-forming. Carisoprodol should not be used as its active metabolite,

meprobamate is commonly abused. Chronic use of benzodiazepines or any muscle relaxant is **not recommended** due to their habit-forming potential, seizure risk following abrupt withdrawal, and documented contribution to deaths of patients on opioids due to respiratory depression. A number of muscle relaxants interact with other medications.

- ❖ Optimum Duration: 1 week.

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

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

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

ii. Non-Selective Non-Steroidal Anti-Inflammatory Drugs:

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

- ❖ Optimal Duration: 1 week.

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

iii. Selective Cyclo-oxygenase-2 (COX-2) Inhibitors:

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

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

- ❖ Optimal Duration: 7 to 10 days.
- ❖ Maximum Duration: Chronic use is appropriate in individual cases. Use of these substances long-term (3 days per week or greater) is associated with rebound pain upon cessation.

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

Opioids medications should be prescribed with strict time, quantity, and duration guidelines, and with definitive cessation parameters. Pain is subjective in nature and should be evaluated using a pain scale and assessment of function to rate effectiveness of the opioid prescribed. Any use beyond the maximum should be documented and justified based on the diagnosis and/or invasive procedures. Adverse effects include respiratory depression, impaired alertness, and the development of physical and psychological dependence.

- ❖ Optimum Duration: Up to 7 days.
- ❖ Maximum Duration: 2 weeks. Use beyond 2 weeks is acceptable in appropriate cases when functional improvement is documented. Refer to the Division's Chronic Pain Disorder Medical Treatment Guidelines, which give a detailed discussion regarding medication use in chronic pain management. Use beyond 30 days after non-traumatic injuries, or 6 weeks post-surgery after the original injury or post-operatively is **not recommended**. If necessary, the physician should access the Colorado Prescription Drug Monitoring Program (PDMP) and follow recommendations in the Chronic Pain Guideline. This system allows the

prescribing physician to see most of the controlled substances prescribed by other physicians for an individual patient.

- 6. EDUCATION/INFORMED DECISION MAKING** of the patient and family, as well as the employer, insurer, policy makers and the community should be the primary emphasis in the treatment of TOS pain and disability. Unfortunately, practitioners often think of education and informed decision making last, after medications, manual therapy, and surgery.

Informed decision making is the hallmark of a successful treatment plan. In most cases, the continuum of treatment from the least invasive to the most invasive (e.g. surgery) should be discussed. The intention is to find the treatment along this continuum that most completely addresses the condition. Patients should identify their personal functional goals of treatment at the first visit. It is recommended that specific individual goals are articulated at the beginning of treatment as this is likely to lead to increased patient satisfaction above that achieved from improvement in pain or other physical function. Progress toward the individual functional goals identified should be addressed at follow up visits and throughout treatment by other members of the health care team as well as the authorized physicians.

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

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

Before diagnostic tests or referrals for invasive treatment take place the patient should be able to clearly articulate the goals of the intervention, the general side effects and risks associated with it and their decision regarding compliance with the suggested plan. There is some evidence that information provided only by video is not sufficient education.

Practitioners must develop and implement an effective strategy and skills to educate patients, employers, insurance systems, policy makers, and the community as a whole. An education-based paradigm should always start with providing reassuring information to the patient and informed decision making. More in-depth education currently exists within a treatment regimen employing functional restoration, prevention, and cognitive behavioral techniques. Patient education and informed decision making should facilitate self-management of symptoms and prevention.

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

- 7. PERSONALITY/PSYCHOSOCIAL/PSYCHOLOGICAL INTERVENTION:** Psychosocial treatment is a well-established therapeutic and diagnostic intervention with selected use

in acute pain problems and more widespread use in sub-acute and chronic pain populations. Psychosocial treatment is recommended as an important component in the total management of a patient with chronic pain and should be implemented as soon as the problem is identified.

If a diagnosis consistent with the standards of the American Psychiatric Association's Diagnostic and Statistical Manual of Mental Disorders (DSM) has been determined, the patient should be evaluated for the potential need for psychiatric medications. Use of any medication to treat a diagnosed condition may be ordered by the authorized treating physician or by the consulting psychiatrist. Visits for management of psychiatric medications are medical in nature and are not a component of psychosocial treatment. Therefore, separate visits for medication management may be necessary, depending on the patient and medications selected.

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

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

A psychologist with a PhD, PsyD, EdD credentials, or a psychiatric MD/DO may perform psychosocial treatments. Other licensed mental health providers or licensed health care providers with training in CBT, or certified as CBT therapists who have experience in treating chronic pain disorders in injured workers, may also perform treatment in consultation with a PhD, PsyD, EdD, or psychiatric MD/DO.

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

It should be noted that most clinical trials on CBT exclude subjects who have significant psychiatric diagnoses. Consequently, the selection of patients for CBT should include the following considerations. CBT is instructive and structured, using an educational model with homework to teach inductive rational thinking. Because of this educational model, a certain level of literacy is assumed for most CBT protocols. Patients who lack the cognitive and educational abilities required by a CBT protocol are unlikely to be successful. Further, given the highly structured nature of CBT, it is more effective when a patient's circumstances are relatively stable. For example, if a patient is about to be

evicted, is actively suicidal, or is coming to sessions intoxicated, these matters will generally preempt CBT treatment for pain, and require other types of psychotherapeutic response. Conversely, literate patients whose circumstances are relatively stable, but who catastrophize or cope poorly with pain or disability are often good candidates for CBT for pain. Similarly, literate patients whose circumstances are relatively stable, but who exhibit unfounded medical phobias, are often good candidates for CBT for anxiety.

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

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

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

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

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

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

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

- ❖ Maximum Duration: 16 sessions.

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

b. Other Psychological/Psychiatric Interventions:

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

8. RESTRICTION OF ACTIVITIES: Continuation of normal daily activities is the recommendation for most patients since immobility will negatively affect rehabilitation. Prolonged immobility results in a wide range of deleterious effects, such as a reduction in aerobic capacity and conditioning, loss of muscle strength and flexibility, increased segmental stiffness, promotion of bone demineralization, impaired disc nutrition, and the facilitation of the illness role. Mobility is generally therapeutic and should be encouraged. Activity should be increased based on the improvement of core strengthening.

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

9. RETURN-TO-WORK: Return to work and/or work-related activities whenever possible is one of the major components in treatment and rehabilitation. Return to work is a subject that should be addressed by each workers' compensation provider at the first meeting with the injured employee and updated at each additional visit. A return-to-work format should be part of a company's health plan, knowing that return to work can decrease anxiety, reduce the possibility of depression, and reconnect the worker with society.

Because a prolonged period of time off work will decrease the likelihood of return to work, the first weeks of treatment are crucial in preventing and/or reversing chronicity and disability mindset. In complex cases, experienced nurse case managers may be required to assist in return to work. Other services, including psychological evaluation and/or treatment, jobsite analysis, and vocational assistance, may be employed.

Two counseling sessions with an occupational physician, and work site visit if necessary, may be helpful for workers who are concerned about returning to work.

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

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

- a.** **Job History Interview:** The authorized treating physician should perform a job history interview at the time of the initial evaluation and before any plan of treatment is established. Documentation should include the workers' job demands, stressors, duties of current job, and duties of job at the time of the initial injury. In addition, cognitive and social issues should be identified, and treatment of these issues should be incorporated into the plan of care.
- b.** **Coordination of Care:** Management of the case is a significant part of return to work and may be the responsibility of the authorized treating physician, occupational health nurse, risk manager, or others. Case management is a method of communication between the primary provider, referral providers, insurer, employer, and employee. Because case management may be coordinated by a variety of professionals, the case manager should be identified in the medical record.
- c.** **Communication:** This is essential between the patient, authorized treating physician, employer, and insurer. Employers should be contacted to verify employment status, job duties and demands, and policies regarding injured workers. In addition, the availability and duration of temporary and permanent restrictions, as well as other placement options, should be discussed and documented. All communications in the absence of the patient are required to be documented and made available to the patient.
- d.** **Establishment of Return-to-Work Status:** Return to work for persons with chronic pain should be considered therapeutic, assuming that work is not likely to aggravate the basic problem or increase the discomfort. In most cases of chronic pain, the worker may not be currently working or even employed. The goal of return to work would be to implement a plan of care to return the worker to any level of employment with the current employer or to return him/her to any type of new employment. Temporary restrictions may be needed while recommended ergonomic or adaptive equipment is obtained; employers should obtain recommended equipment in a timely manner.
- e.** **Establishment of Activity Level Restrictions:** A formal job description for the injured worker is necessary to identify physical demands at work and assist in the creation of modified duty. A jobsite evaluation may be utilized to identify applicable tasks such as pushing, pulling, lifting, reaching, grasping, pinching, sitting, standing, posture, ambulatory distance and terrain, and if applicable, environment for temperature, air flow, noise, and the number of hours that may be worked per day. Due to the lack of predictability regarding exacerbation of symptoms affecting function, an extended, occupationally focused functional capacity evaluation may be necessary to determine the patient's tolerance for job type tasks over a continued period of time. Job requirements should be reviewed

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

- f. Rehabilitation and Return to Work:** As part of rehabilitation, every attempt should be made to simulate work activities so that the authorized treating physician may promote adequate job performance. The use of ergonomic or adaptive equipment, therapeutic breaks, and interventional modalities at work may be necessary to maintain employment.
- g. Vocational Assistance:** Formal vocational rehabilitation is a generally accepted intervention and can assist disabled persons to return to viable employment. Assisting patients to identify vocational goals will facilitate medical recovery and aid in the achievement of MMI by (1) increasing motivation towards treatment and (2) alleviating the patient's emotional distress. Physically limited patients will benefit most if vocational assistance is provided during the interdisciplinary rehabilitation phase of treatment. To assess the patient's vocational capacity, a vocational assessment utilizing the information from occupational and physical therapy assessments may identify rehabilitation program goals. This assessment also may optimize both patient motivation and utilization of rehabilitation resources. This may be extremely helpful in decreasing the patient's fear regarding an inability to earn a living, which can add to his/her anxiety and depression.

Recommendations to Employers and Employees of Small Businesses: employees of small businesses who are diagnosed with chronic pain may not be able to perform any jobs for which openings exist. Temporary employees may fill those slots while the employee functionally improves. Some small businesses hire other workers, and if the injured employee returns to the job, the supervisor/owner may have an extra employee. To avoid this, it is suggested that case managers be accessed through their payer or third-party administrator. Case managers may assist with resolution of these problems, as well as assist in finding modified job tasks, or find jobs with reduced hours, etc., depending on company philosophy and employee needs.

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

- 10. 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 physical 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.

Abnormal posture, head tilting forward and scapular dyskinesia are frequently contributors to thoracic outlet symptoms. These tip the scapula anteriorly, altering motor control of the scapulothoracic and glenohumeral articulations. The most noticeable feature is prominence of the inferior angle of the scapula. Dysfunction of the pectoralis minor and other scapular muscles places the acromion closer to the rotator cuff and humeral head, compromising the subacromial space. The altered relations of length and tension of the deltoid and cuff muscles results in poor motor control of the humerus on the glenoid fossa.

The use and integration of active and passive therapies should be directed at addressing impairments found in the clinical examination which may include abnormal posture, head tilting forward, scapula dyskinesia and joint/tissue hypomobility/hypermobility. These clinical findings are frequently contributors to the thoracic outlet symptoms and many times result in scapula anterior tipping and altered motor control of the scapula/thoracic and glenohumeral joints. In this classification of scapula dysfunction, the primary external visual feature is the anterior tilting of the scapula in the sagittal plane which produces the prominent inferior angle of the scapula. Many times the anterior tilting is associated with shortening of the pectoralis minor and poor function of the scapula muscles controlling the inferior angle. This myofascial and scapula dysfunction places the acromion in a position closer to the rotator cuff and humeral head and can thereby compromise the subacromial space. Additionally, this resultant scapula dyskinesia disrupts the length tension relationships of the shoulder complex's static and dynamic constraints and subsequently facilitates poor humeral head positioning on the glenoid. (The static constraints are the glenohumeral ligaments and the dynamic constraints are the deltoid and cuff musculature.) Therefore the treatment of this scapula dyskinesia and myofascial dysfunction is important for restoration of the normal upper quarter function.

The healthy function of the upper body is inextricably dependent on the proper function and balanced relationships with its neighboring structures: cervical, thoracic, costal, when one acknowledges the role of fascia, particularly the thoracodorsal fascia. Therefore, effective and expedient rehabilitation requires providers to have an excellent understanding of the functional anatomy of these structures and their dynamic inter-relatedness. Shoulder injuries are complex. Successful treatment of these injuries requires the providers to have expert skills. Collaboration is essential in achieving optimal outcomes.

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 use of a patient completed pain drawing, VAS, and functional outcome tools is highly recommended to help providers track progress. Functional objective goals including minimum clinically important difference (MCID) of the functional tools should be monitored and documented regularly to determine the effectiveness of treatment.

On occasion, specific diagnoses and post-surgical conditions may warrant durations of treatment beyond those listed as "maximum." Factors such as exacerbation of symptoms, re-injury, interrupted continuity of care and comorbidities may also extend durations of

care. Specific goals with objectively measured functional improvement during treatment must be cited to justify extended durations of care. It is recommended that, if no functional gain is observed after the number of treatments under “time to produce effect” have been completed, then alternative treatment interventions, further diagnostic studies, or further consultations should be pursued.

The following active therapies are listed in alphabetical order:

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

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

b. Aquatic Therapy: is a well-accepted treatment which consists of using aquatic immersion for therapeutic exercise to promote range-of-motion, core stabilization, endurance, flexibility, strengthening, 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. Literature has shown that the muscle recruitment for aquatic therapy versus similar non-aquatic motions is significantly less. Because there is always a risk of recurrent or additional damage to the muscle tendon unit after a surgical repair, aquatic therapy may be preferred by surgeons to gain early return of range of motion. In some cases, the patient will be able to do the exercises unsupervised after the initial supervised session. Parks and recreation contacts may be used to develop less expensive facilities for patients. Indications include:

- Postoperative therapy as ordered by the surgeon; or
- Intolerance for active land-based or full-weight bearing therapeutic procedures; or
- Symptoms that are exacerbated in a dry environment; and
- Willingness to follow through with the therapy on a regular basis.

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

- ❖ Time to Produce Effect: 4 to 5 treatments.
- ❖ Frequency: 3 to 5 times per week.

- ❖ Optimum Duration: 4 to 6 weeks.
- ❖ Maximum Duration: 8 weeks.

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

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

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

d. Nerve Gliding: is an accepted therapy for TOS. Nerve gliding exercises consist of a series of gentle movements of the neck, shoulder and arm that produce longitudinal movement along the length of the nerves of the upper extremity. These exercises are based on the principle that the tissues of the peripheral nervous system are designed for movement, and glide (excursion) of nerves may have an effect on neurophysiology through alterations in vascular and axoplasmic flow. Biomechanical principles have been more thoroughly studied than clinical outcomes. The exercises should be done by the patient after proper instruction and monitoring by the therapist.

- ❖ Time to Produce Effect: 2 to 4 weeks.
- ❖ Frequency: Up to 5 times per day by patient (patient-initiated).
- ❖ Optimum Duration: 4 to 6 sessions.
- ❖ Maximum Duration: 6 to 8 sessions.

e. Neuromuscular Re-education: is a generally accepted treatment. Neuromuscular re-education 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. Changes in posture and scapula movements are important to restore normal upper quarter movements and minimize thoracic outlet symptoms. 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. Muscles that should be targeted for correct timing and recruitment include the serratus anterior, upper trapezius, lower trapezius, and middle trapezius. Accessory stabilizers including the rhomboids, latissimus dorsi and levator scapula should also be addressed to assist with scapula setting. Normal scapula positioning and movements should be the goal of the neuromuscular re-education. Furthermore,

the limitations in flexibility and motor control of the pectoralis minor are a common incriminator with this type of dysfunction.

- ❖ Time to Produce Effect: 2 to 6 treatments.
- ❖ Frequency: 3 times per week.
- ❖ Optimum Duration: 4 to 8 weeks.
- ❖ Maximum Duration: 8 weeks. Additional visits may be necessary in cases of re-injury, interrupted continuity of care, exacerbation of symptoms, and in those patients with comorbidities. Functional gains including increased range of motion must be demonstrated to justify continuing treatment.

f. Therapeutic Exercise: is a generally well-accepted treatment. Therapeutic exercise with or without mechanical assistance or resistance, may include manual facilitation, isoinertial, isotonic, isometric and isokinetic types of exercises. The exact type of program and length of therapy should be determined by the treating physician with the physical or occupational therapist. In most cases the therapist instructs the patient in a supervised clinic and home program to increase motion with tissue elasticity and subsequently increase strength and endurance. Usually, manual therapy is performed initially to assure correct muscle activation followed by isometrics and progressing to isotonic exercises as tolerated.

- ❖ Time to Produce Effect: 2 to 6 treatments.
- ❖ Frequency: 2 to 3 times per week.
- ❖ Optimum Duration: 16 to 24 sessions.
- ❖ Maximum Duration: 36 sessions. Additional visits may be necessary in cases of re-injury, interrupted continuity of care, exacerbation of symptoms, and in those patients with comorbidities. Functional gains including increased range of motion must be demonstrated to justify continuing treatment.

11. THERAPY – PASSIVE:

The following passive therapies and modalities are generally accepted methods of care for a variety of work-related injuries. Passive therapy includes those treatment modalities that do not require energy expenditure on the part of the patient. They are principally effective during the early phases of treatment and are directed at controlling symptoms such as pain, inflammation and swelling and to improve the rate of healing soft tissue injuries. They should be used adjunctively with active therapies such as postural stabilization and exercise programs to help control swelling, pain and inflammation during the rehabilitation process. Please refer to Section B.4, General Guidelines Principles, Active Interventions. Passive therapies may be used intermittently as a therapist deems appropriate or regularly if there are specific goals with objectively measured functional improvements during treatment.

On occasion, specific diagnoses and post-surgical conditions may warrant durations of treatment beyond those listed as "maximum." Factors such as exacerbation of symptoms,

re-injury, interrupted continuity of care and comorbidities may also extend durations of care. Specific goals with objectively measured functional improvement during treatment must be cited to justify extended durations of care. It is recommended that, if no functional gain is observed after the number of treatments under “time to produce effect” has been completed, alternative treatment interventions, further diagnostic studies, or further consultations should be pursued.

The following passive therapies and modalities are listed in alphabetical order.

a. Electrical Stimulation (Unattended): is an accepted treatment. Once applied, electrical stimulation (unattended) requires minimal on-site supervision by the physical therapists, occupational therapist or other provider. Indications include pain, inflammation, muscle spasm, atrophy, decreased circulation, and the need for osteogenic stimulation. A home unit should be purchased if treatment is effective and frequent use is recommended.

- ❖ Time to Produce Effect: 2 to 4 treatments.
- ❖ Frequency: Varies, depending upon indication, between 2 to 3 times/day to 1 time/week.
- ❖ Optimum Duration: 1 month.
- ❖ Maximum Duration: Use beyond 6 weeks requires a home unit.

b. 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, dexamethasone), edema (mecholy, hyaluronidase, and salicylate), ischemia (magnesium, mecholy, and iodine), muscle spasm (magnesium, calcium), calcifying deposits (acetate), scars, and keloids (sodium chloride, iodine, acetate). An experimental study with healthy human volunteers showed that an iontophoretic preparation of dexamethasone phosphate penetrated up to a depth of 12 mm, but even after 400 minutes following iontophoresis, half of the dexamethasone had penetrated no deeper than 2 mm. Iontophoresis appears to be effective only in superficial tissues. Per the Colorado Physical Therapy Practice Act, referring physician must write a prescription for medication, and the individual must bring the medication (not the prescription for medication) to the treating therapist for use in iontophoresis.

- ❖ Time to Produce Effect: 1 to 4 treatments.
- ❖ Frequency: 3 times per week with at least 48 hours between treatments.
- ❖ Optimum Duration: 8 to 10 treatments.
- ❖ Maximum Duration: 10 treatments.

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

High velocity, low amplitude (HVLA) technique, chiropractic manipulation, osteopathic manipulation, muscle energy techniques, counter strain, and non-force techniques are all types of manipulative treatment. This may be applied by osteopathic physicians (D.O.), chiropractors (D.C.), properly trained physical therapists (P.T.), properly trained occupational therapists (O.T.), or properly trained medical physicians. Under these different types of manipulation exist many subsets of different techniques that can be described as a) direct- a forceful engagement of a restrictive/pathologic barrier, b) indirect- a gentle/non-forceful disengagement of a restrictive/pathologic barrier, c) the patient actively assisting 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. Mobilization may be directed at the first rib and the scapula.

- ❖ Time to produce effect for all types of manipulative treatment: 1 to 6 treatments.
- ❖ Frequency: Up to 3 times per week for the first 3 weeks as indicated by the severity of involvement and the desired effect.
- ❖ Optimum Duration: 10 treatments.
- ❖ Maximum Duration: 12 treatments. Additional visits may be necessary in cases of re-injury, interrupted continuity of care, exacerbation of symptoms, and in those patients with comorbidities. Functional gains including increased range of motion must be demonstrated to justify continuing treatment.

d. Massage-Manual or Mechanical: is a generally well-accepted treatment. Massage is manipulation of soft tissue with broad ranging relaxation and circulatory benefits. This may include stimulation of acupuncture points and acupuncture channels (acupressure), application of suction cups and techniques that include pressing, lifting, rubbing, pinching of soft tissues by, or with the practitioner's hands. Indications include edema (peripheral or hard and non-pliable edema), muscle spasm, adhesions, the need to improve peripheral circulation and range of motion, or to increase muscle relaxation and flexibility prior to exercise. In cases with edema, deep vein thrombosis should be ruled out prior to treatment.

- ❖ Time to Produce Effect: Immediate.
- ❖ Frequency: 1 to 2 times per week.
- ❖ Optimum Duration: 6 weeks.
- ❖ Maximum Duration: 2 months.

e. Mobilization (Joint): is a generally well-accepted treatment. Mobilization is passive movement, which may include passive range of motion performed in such a manner (particularly in relation to the speed of the movement) that it is, at

all times, within the ability of the patient to prevent the movement if they so choose. 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. Mobilization may be directed at the first rib and the scapula.

- ❖ Time to Produce Effect: 6 to 9 treatments.
- ❖ Frequency: 3 times per week.
- ❖ Optimum Duration: 6 weeks.
- ❖ Maximum Duration: 2 months.

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

- ❖ Time to Produce Effect: 2 to 3 weeks.
- ❖ Frequency: 2 to 3 times per week.
- ❖ Optimum Duration: 4 to 6 weeks.
- ❖ Maximum Duration: 6 weeks.

g. **Superficial Heat and Cold Therapy:** is a generally accepted treatment. Superficial heat and cold therapies 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. It may be used acutely with compression and elevation. Indications include acute pain, edema and hemorrhage, need to increase pain threshold, reduce muscle spasm and promote stretching/flexibility. Includes portable cryotherapy units and application of heat just above the surface of the skin at acupuncture points.

- ❖ Time to Produce Effect: Immediate.
- ❖ Frequency: 2 to 5 times per week.
- ❖ Optimum Duration: 3 weeks as primary, or up to 2 months if used intermittently as an adjunct to other therapeutic procedures.
- ❖ Maximum Duration: 2 months.

h. **Transcutaneous Electrical Nerve Stimulation (TENS):** is a generally accepted treatment and should include at least one instructional session for proper application and use. Indications include muscle spasm, atrophy, and decreased circulation and pain control. Minimal TENS unit parameters should include pulse

rate, pulse width and amplitude modulation. Consistent, measurable functional improvement must be documented prior to the purchase of a home unit.

- ❖ Time to Produce Effect: Immediate.
- ❖ Frequency: Variable.
- ❖ Optimum Duration: 3 sessions.
- ❖ Maximum Duration: 3 sessions. If beneficial, provide with home unit or purchase if effective.

i. Ultrasound (including Phonophoresis): is an accepted treatment and includes ultrasound with electrical stimulation and phonophoresis. Ultrasound uses sonic generators to deliver acoustic energy for therapeutic thermal and/or non-thermal soft tissue effects. Indications include scar tissue, adhesions, 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 a dispersive electrode placement. Indications include muscle spasm, scar tissue, pain modulation, and muscle facilitation.

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

- ❖ Time to Produce Effect: 6 to 15 treatments.
- ❖ Frequency: 3 times per week.
- ❖ Optimum Duration: 4 to 8 weeks.
- ❖ Maximum Duration: 2 months.

12. VOCATIONAL REHABILITATION: is a generally accepted intervention, but Colorado limits its use as a result of Senate Bill 87-79. Initiation of vocational rehabilitation requires adequate evaluation of patients for quantification highest functional level, motivation and achievement of maximum medical improvement. Vocational rehabilitation may be as simple as returning to the original job or as complicated as being retrained for a new occupation.

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

G. THERAPEUTIC PROCEDURES - OPERATIVE

All operative interventions must be based upon positive correlation of clinical findings, clinical course, and diagnostic tests. A comprehensive assimilation of these factors must lead to a specific diagnosis with positive identification of pathologic condition(s). It is imperative to rule out non-physiologic modifiers of pain presentation or non-operative conditions mimicking operative conditions (e.g., peripheral neuropathy, myofascial pain, scleratogenous or sympathetically mediated pain syndromes, psychological), prior to consideration of elective surgical intervention. Operative procedures are only appropriate for Neurogenic or Vascular TOS as defined below. Patients with thoracic outlet symptoms due to myofascial issues are not surgical candidates.

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

Structured rehabilitation interventions should be strongly considered post-operative in any patient not making expected functional progress within three weeks post-operative.

Post-operative therapy will frequently require a repeat of the therapy provided pre-operatively. Refer to Section F. Therapeutic Procedures, Non-operative, and consider the first post-operative visit as visit number one, for the time frame parameters provided.

Return-to-work restrictions should be specific according to the recommendation in Section F.10, Therapeutic Procedures – Non-operative.

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

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

1. NON-VASCULAR (DIAGNOSTIC CRITERIA FOR SURGICAL PROCEDURES):

a. Neurogenic TOS:

- i. Clinical: at least two consistent clinical signs plus symptoms consistent with TOS (Refer to Section D. Initial Diagnostic Procedures).
- ii. Neurophysiologic: meets criteria for neurogenic TOS (Refer to Section E.2.a Electromyography/Nerve Conduction Velocities (EMG/NCV)).
- iii. The following diagnoses may present similarly to TOS and should be investigated and eliminated to establish the diagnosis: Cervical herniated

disc or spondylosis, complex regional pain syndrome, other peripheral nerve disorders or brachial plexus neuritis, tumors or space occupying lesions, cervical dystonia, opioid hyperalgesia, and shoulder conditions.

b. **Pectoralis Minor Syndrome without TOS:**

Compression of the neurovascular bundle by the pectoralis muscle. This syndrome, described by a few authors, is usually caused by neck or shoulder trauma and generally resolves with physical therapy.

- i. Clinical: Patients do not meet criteria for neurogenic TOS. They generally have pain over the anterior chest wall near the pectoralis minor and into the axilla, arm, and forearm. They may complain of paresthesia or weakness, and have fewer complaints of headache, neck or shoulder pain. On physical exam there is tenderness with palpation over the pectoralis minor and in the axilla which reproduces the patient's symptoms in the arm. Disabling symptoms have been present for more than 3 months despite active participation in an appropriate therapy program and alternative diagnoses have been explored and tests are negative.
- ii. Neurophysiologic and other diagnostic tests: EMG/NCV studies may show medial antebrachial cutaneous nerve changes compared to the normal side. The axillary vein may show some occlusion. Pectoralis minor block should be positive.

2. **SURGICAL INDICATIONS:**

a. Early surgical intervention should be performed if there is:

- i. Documented EMG/NCV evidence of nerve compression with sensory loss, and weakness (with or without muscle atrophy) **or**
- ii. Acute subclavian vein thrombosis or arterial thrombosis; or
- iii. Subclavian artery aneurysm or stenosis secondary to a cervical or anomalous rib (Note: this condition is almost never work related.)

b. If early surgery is not indicated, surgery may be performed after failed conservative therapy. The following criteria must be fulfilled.
Note: Workers compensation status has been found to predict a poor outcome in several studies, thus all criteria should be met for operative procedures.

- i. Neurogenic: see criteria in the preceding subsection; and
- ii. Failed 3 months of active participation in non-operative therapy including worksite changes; and
- iii. Disabling symptoms interfering with work, recreation, normal daily activities, sleep; and
- iv. Pre-surgical psychiatric or psychological evaluation and clearance has been obtained, demonstrating motivation and long-term commitment without major issues of secondary gain or other psychological

contraindications for surgery, and with an expectation that surgical relief of pain probably would improve the patient's functioning.

A long-term follow-up study of patients having surgery for neurogenic TOS reported that disability at 4 years postoperatively was strongly related to the presence of major depression, as evaluated by the Beck Depression Inventory taken preoperatively. The adjusted odds ratio for depression and disability was 15.7. Even though the response rate for the four-year survey was only 58% of the eligible population, the association between preoperative depression and long-term disability was robust and not likely to be vulnerable to nonresponse bias. Refer to Section E.7 Personality/Psychological/Psychosocial Evaluations.

- c.** Even if return to their prior job is unlikely, an individual may need surgical intervention to both increase activities-of-daily living and/or return-to-work in a different job.
- d.** It is critically important that all other pathology be treated prior to surgical intervention for TOS. Other pathologies were commonly diagnosed in this population. Comorbid conditions of the shoulder, cervical spine, and carpal tunnel should be treated or ruled out before surgery is considered.
- e.** Smoking may affect soft tissue healing through tissue hypoxia. Patients should be strongly encouraged to stop smoking and provided with appropriate counseling.
- f.** Prior to surgical intervention, the patient and treating physician should identify functional operative goals and the likelihood of achieving improved ability to perform activities of daily living or work activities. The patient should agree to comply with the pre- and post-operative treatment plan including home exercise requirements. The patient should understand the amount of post-operative therapy required and the length of partial and full disability expected post operatively. Certain comorbidities predict less favorable outcomes: chronic pain syndrome, use of opioids, smoking, and age over forty.

3. SURGICAL PROCEDURES:

Since the success rates for the various surgical procedures are similar, the Division suggests that the surgeon performing the procedure use the technique with which the surgeon has the most experience and is most appropriate for the patient.

Vascular TOS procedures include resection of the abnormal rib and repair of the involved vessel. Anticoagulation is required for thrombotic cases.

- a.** First rib resection.
- b.** Anterior and middle scalenectomy.
- c.** Anterior scalenectomy.
- d.** Combined first rib resection and scalenectomy.
- e.** Pectoralis minor tenotomy. This procedure is done under local anesthesia, normally in an out-patient setting for patients meeting the criteria for pectoralis

minor syndrome. Return to activity and work occurs early, with full range of motion at 3 days and 85% return to continuing work. Complication rate is lower than for other procedures.

- 4.** **COMPLICATIONS:** Complications and/or unsatisfactory outcomes are reportedly in the range of 10 to 20%. Acknowledged complications depend on the procedure and include complex regional pain syndrome; Horner's syndrome; lymphocele; permanent brachial plexus damage; phrenic, intercostal brachial cutaneous or long thoracic nerve damage; and pneumothorax.

5. **POST-OPERATIVE TREATMENT:**

Individualized rehabilitation programs based upon communication between the surgeon and the therapist.

- a.** Overhead activities and lifting are usually avoided for 2 to 4 weeks. Therapy programs should address any identified neuromuscular or posture abnormalities. Generally, progressive resistive exercises no earlier than 2 months post-operatively with gradual return to full activity at 4 months.
- b.** Return-to-work and restrictions after surgery may be made by an experienced primary occupational medicine physician in consultation with the surgeon or by the surgeon. Depending upon the patient's functional response and their job requirements, return-to-work with job modifications may be considered as early as one week post operatively. The employer must be able to fully accommodate restrictions of overhead activities or heavy lifting. Work restrictions should be evaluated every 4 to 6 weeks during post-operative recovery and rehabilitation, with appropriate written communications to both the patient and the employer.
- c.** Should progress plateau, the provider should re-evaluate the patient's condition and make appropriate adjustments to the treatment plan.
- d.** Post-operative therapy will frequently require a repeat of the therapy provided pre-operatively. Refer to Section F. Therapeutic Procedures, Non-operative, and consider the first post-operative visit as visit number one for the time frame parameters provided.
- e.** Refer to the following areas in the non-operative therapeutic section for post-operative time parameters.
- Activities of daily living.
 - Functional activities.
 - Nerve gliding.
 - Neuromuscular re-education.
 - Therapeutic exercise.
 - Proper work techniques: Refer to Section E.8.c. Jobsite Evaluation, and Section F.10. Return-to-Work of these guidelines.
 - Limited passive therapies may be appropriate in some cases.