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Washington State Department of Labor & Industries

Work-Related Neurogenic Thoracic Outlet Syndrome Diagnosis and Treatment*

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**This guideline does not apply to severe or acute traumatic injury of the upper extremities, nor to vascular categories of TOS.*

Effective October 1, 2010; Appendix for Cervicobrachial Syndrome added February 2019

I. Guideline Summary

Review Criteria for the Diagnosis and Treatment of Work-Related Neurogenic Thoracic Outlet Syndrome (nTOS)				
CLINICAL FINDINGS			CONSERVATIVE TREATMENT	SURGICAL TREATMENT
SUBJECTIVE (Symptoms)	**OBJECTIVE (Signs)**	**DIAGNOSTIC**		
AND		**AND**		
Pain, paresthesias, or weakness affecting the upper extremity (most commonly affecting the ring or small finger)	Tenderness Scalene Trapezius Anterior chest wall Brachial plexus Weakness Loss of finger dexterity Atrophy	Electrodiagnostic studies (EDS) are required to objectively confirm the diagnosis of nTOS. <u>EDS criteria are as follows:</u> 1. Absent or reduced amplitude (< 12 uV) of the ulnar SNAP OR Absent or reduced amplitude (< 10 uV) of the medial antebrachial cutaneous nerve (MABC) SNAP with normal amplitude of the MABC SNAP in the contralateral (unaffected) extremity AND 2. Absent or reduced amplitude (< 5 mV) of the median CMAP OR Absent or prolonged minimum latency (>33 msec) of the ulnar F-wave (with or without abnormalities of the median F-wave), and with normal F-waves in the contralateral (unaffected) upper extremity OR Needle electromyography (EMG) showing denervation (e.g. fibrillation potentials, positive sharp waves) in at least one muscle supplied by each of two different nerves from the lower trunk of the brachial plexus, with normal EMG of the cervical paraspinal muscles and at least one muscle supplied by a nerve from the middle or upper trunk of the brachial plexus AND 3. Normal amplitude (≥ 15uV) of the median nerve SNAP AND 4. Normal conduction velocity (≥ 50m/s) of the ulnar motor nerve across the elbow	Modify job activities that exacerbate symptoms AND/OR Physical therapy with strengthening and stretching, postural exercises AND/OR Anti-inflammatory drug therapy	Surgical treatment should only be considered if: 1. The patient has met the diagnostic criteria under Section III AND 2. The condition interferes with work or activities of daily living AND 3. The condition does not improve despite conservative treatment Without confirmation of brachial plexus compression **by both objective clinical findings and abnormal EDS**, surgery will not be authorized.

II. Introduction

This guideline is to be used by physicians, claim managers, occupational nurses, and utilization review staff. The emphasis is on accurate diagnosis and treatment that is curative or rehabilitative (see WAC 296-20-01002 for definitions). An electrodiagnostic worksheet and guideline summary are appended to the end of this document.

This guideline was developed in 2010 by the Washington State's Industrial Insurance Medical Advisory Committee (IIMAC) and its subcommittee on Upper Extremity Entrapment Neuropathies. The subcommittee presented its work to the full IIMAC, and the IIMAC voted with full consensus advising the Washington State Department of Labor & Industries to adopt the guideline. This guideline was based on the weight of the best available clinical and scientific evidence from a systematic review of the literature* and a consensus of expert opinion. One of the Committee's primary goals is to provide standards that ensure high quality of care for injured workers in Washington State.

Thoracic Outlet Syndrome (TOS) is characterized by pain, paresthesias, and weakness in the upper extremity, which may be exacerbated by elevation of the arms or by exaggerated movements of the head and neck. There are three categories of thoracic outlet syndrome: arterial, venous and neurogenic. Arterial and venous thoracic outlet syndromes involve obstruction of the subclavian artery or vein, respectively, as they pass through the thoracic outlet. These vascular categories of TOS should include obvious clinical signs of vascular insufficiency: a cold, pale extremity in the case of arterial TOS, or a swollen, cyanotic extremity in the case of venous TOS. There is a separate surgical guideline for vascular TOS. This guideline focuses solely on non-acute, neurogenic TOS (nTOS).

Work-related nTOS occurs due to compression of the brachial plexus, predominantly affecting its lower trunk, at one of three potential sites. Compression can occur between the anterior and middle scalene muscles (or sometimes through the anterior scalene muscle); beneath the clavicle in the costoclavicular space; or beneath the tendon of the pectoralis minor.[1]

The medical literature describes two categories of nTOS: “true” nTOS and “disputed” nTOS. A diagnosis of true nTOS requires electrodiagnostic study (EDS) abnormalities showing evidence of brachial plexus injury. Disputed nTOS describes cases of nTOS for which EDS abnormalities have not been demonstrated. To avoid confusion that has arisen over these categories, this guideline does not use such terms. Rather, it provides guidance regarding treatment for cases of nTOS that have been confirmed by EDS abnormalities compared with those cases for which the provisional diagnosis has not been confirmed by such studies.

In general, work-relatedness and appropriate symptoms and objective signs must be present for Labor and Industries to accept nTOS on a claim. Electrodiagnostic studies (EDS), including nerve conduction velocity studies (NCVs) and needle electromyography (EMG), should be scheduled immediately to confirm the clinical diagnosis. If time loss extends beyond two weeks or if surgery is requested, completion of EDS is required and does not need prior authorization.

* Evidence was classified using criteria defined by the American Academy of Neurology (see references)

III. Establishing Work-relatedness

Work-related activities may cause or contribute to the development of nTOS.[2,3] Because simply identifying an association with workplace activities is not, in itself, adequate evidence of a causal relationship, establishing work-relatedness requires all of the following:

1. Exposure: Workplace activities that contribute to or cause nTOS, and
2. Outcome: A diagnosis of nTOS that meets the diagnostic criteria under Section III, and
3. Relationship: Generally accepted scientific evidence, which establishes on a more probable than not basis (greater than 50%) that the workplace activities (exposure) in an individual case contributed to the development or worsening of the condition (outcome).

When the Department receives notification of an occupational disease, the Occupational Disease & Employment History form is mailed to the worker, employer or attending provider. The form should be completed and returned to the insurer as soon as possible. If the worker's attending provider completes the form, provides a detailed history in the chart note, and gives an opinion on causality, he or she may be paid for this (use billing code 1055M). Additional billing information is available in the Attending Provider Resource Center.

Symptoms of nTOS may be exacerbated by certain work-related activities, usually involving elevation or sustained use of the arms. Such activities may include but are not limited to the following[4]:

Lifting overhead	Holding tools or objects above shoulder level
Reaching overhead	Carrying heavy weights

Several occupations have been associated with nTOS. This is **not** an exhaustive list and is meant only as a guide in the consideration of work-relatedness:

Dry wall hanger or plasterer	Assembly line inspector
Welder	Shelf stocker
Beautician	Dental hygienist

IV. Making the Diagnosis

A. Symptoms and Signs

A case definition of confirmed nTOS includes appropriate symptoms, objective physical findings ("signs"), and abnormal EDS. A provisional diagnosis of nTOS may be made based upon appropriate symptoms and objective signs, but confirmation of the diagnosis requires abnormal EDS.
Classic symptoms of nTOS include pain, paresthesias, or weakness in the upper extremity. Paresthesias most commonly affect the ring and small fingers.[5] Symptom severity tends to increase after certain activities and worsens at the end of the day or during sleep.

Signs on examination may include tenderness to palpation over the brachial plexus, the scalene muscles, the trapezius muscles, or the anterior chest wall. Although tenderness may be a useful objective finding, it cannot support the diagnosis of nTOS alone. Advanced cases of nTOS are characterized by objective signs of weakness of the hand, loss of dexterity of the fingers, and atrophy of the affected muscles.

Provocative tests have been described that may help corroborate the diagnosis of nTOS. These tests are based on creating maximal tension on the anatomical sites of constriction. Studies have found a high false-positive rate for these tests in healthy subjects as well as carpal tunnel syndrome patients.[6] Although they are described for completeness, the sensitivity and specificity of these tests for nTOS have not been established, and these tests cannot replace confirmatory EDS testing.

Provocative tests include:

- The elevated arm stress test (EAST or Roos test) - the patient places the affected arm in full abduction and external rotation and then opens and closes the hands slowly for 3 minutes. This test constricts the costoclavicular space. It is considered abnormal if typical symptoms are elicited and the patient cannot sustain this activity for the full 3 minutes.
- The Adson test- the patient extends the neck and rotates the head toward the involved extremity, which is held extended at the side. This test constricts the interscalene triangle. It is considered abnormal if a change in the radial pulse is detected when the patient inhales deeply and holds their breath
- The Wright test- the patient sits or stands with the arm in full abduction and external rotation. This test constricts the costoclavicular space. It is considered abnormal if typical symptoms are elicited and a change in pulse is detected.
- The costoclavicular test- the examiner depresses the patient's shoulder. This test constricts the costoclavicular space and creates tension across the pectoralis minor. It is considered abnormal if typical symptoms are elicited.

Every effort should be made to objectively confirm the diagnosis of nTOS before considering surgery. A differential diagnosis for nTOS includes musculoskeletal disease (e.g. arthritis, tendonitis) of the cervical spine, shoulder girdle or arm, cervical radiculopathy or upper extremity nerve entrapment[7], idiopathic inflammation of the brachial plexus (aka Parsonage-Turner syndrome), and brachial plexus compression due to an infiltrative process or space-occupying mass (e.g. Pancoast tumor of the lung apex). Cervicobrachial Syndrome (CBS) is another possibility that should be carefully considered. Refer to Appendix A for a detailed discussion of this related condition.

B. Electrodiagnostic Studies

EDS abnormalities are required to objectively confirm the diagnosis of nTOS. Given the uncertainties in diagnostic assessment of nTOS, EDS should be obtained as soon as the diagnosis is considered. EDS may help gauge the severity of injury.[8-10] Importantly, EDS can help exclude conditions that may mimic nTOS, such as ulnar nerve entrapment or cervical radiculopathy.[11] EDS evidence that confirms a diagnosis of nTOS requires:

1. Absent or reduced amplitude (< 12 uV) of the ulnar antidromic sensory nerve action potential (SNAP)

Or

Absent or reduced amplitude (< 10 uV) of the medial antebrachial cutaneous nerve (MABC) antidromic SNAP, with normal amplitude of the MABC SNAP in the contralateral (unaffected) extremity

AND

2. Absent or reduced amplitude (<5 mV) of the median nerve compound motor action potential (CMAP)

Or

Absent or prolonged minimum latency (>33 msec) of the ulnar F-wave (with or without abnormalities of the median F-wave), and with normal F-waves in the contralateral (unaffected) upper extremity

Or

Needle electromyography (EMG) showing denervation (e.g. fibrillation potentials, positive sharp

waves) in at least one muscle supplied by each of two different nerves from the lower trunk of the brachial plexus, with normal EMG of the cervical paraspinal muscles and at least one muscle supplied by a nerve from the middle or upper trunk of the brachial plexus.

AND

To exclude the presence of other focal neuropathies or polyneuropathy as a cause for the abnormalities described above, the following must also be shown:

3. Normal amplitude (≥ 15 uV) of the median nerve antidromic SNAP.

AND

4. Normal conduction velocity (≥ 50 m/s) of the ulnar motor nerve across the elbow.

C. Other Diagnostic Tests

Arterial or venous vascular studies may be helpful in the diagnosis of suspected arterial or venous TOS. However, these tests have poor specificity for nTOS, and there is no substantial evidence that vascular studies can reliably confirm the diagnosis of nTOS. Therefore, vascular studies conducted as a diagnostic tool for nTOS will not be authorized.

Some have suggested that magnetic resonance imaging (MRI) neurography may be helpful in the diagnosis of nTOS. However, these services will not be authorized for this condition because the clinical utility of these tests has not yet been proven. While the Committee recognizes that these tests may be useful in unusual circumstances where EDS results are normal but there are appropriate clinical symptoms, the Committee believes that at this time the use of these tests is investigational and should be used only in a research setting.

Anterior scalene muscle (ASM) blocks have been used in the evaluation of suspected nTOS.[12,13] However, this test has poor specificity for nTOS, and there is no substantial evidence that ASM can reliably confirm the diagnosis of nTOS. Therefore, ASM blocks conducted as a diagnostic tool for nTOS will not be authorized.

X-rays of the chest may be useful to evaluate the possibility of an infiltrative process or space-occupying mass (e.g. Pancoast tumor of the lung apex) compressing the brachial plexus.

V. Treatment

Non-surgical therapy may be considered for cases in which a provisional diagnosis of nTOS has been made. Surgical treatment should be provided only for cases in which the diagnosis of nTOS has been confirmed by abnormal EDS. Under these circumstances, the potential benefits of brachial plexus decompression may outweigh the risks of surgery.

A. Conservative Treatment

Conservative treatment for nTOS has been described in narrative reviews, case reports, and retrospective case series.[14-16] No randomized controlled trials have been conducted to measure the efficacy of conservative treatments for nTOS. No specific method of conservative treatment has been proven to be most effective due to a lack of comparative studies.[14] However, an observational study (n=50), showed

that strengthening and stretching exercises reduced pain among 80% of patients after 3 months and among 94% of patients after 6 months[15], and a 2007 systematic review of the available literature concluded that conservative treatment appears to be effective in reducing symptoms, improving function, and facilitating return to work.[14] Examples of conservative treatment include modification of activities that exacerbate symptoms, education, postural exercises, physical therapy, and anti-inflammatory drug therapy.

Because surgical outcomes are poor in many situations, conservative interventions, such as stretching and strengthening exercises, should be considered first. If the initial response to conservative treatment is incomplete, modifying or changing the approach should be considered. If there is no response to conservative treatment within six weeks, or if time loss extends longer than 2 weeks, specialist consultation should be obtained.

Although Botulinum toxin (Botox) injections of the scalene muscles have been reported to relieve nTOS symptoms[17], preliminary results of a randomized trial showed no clear clinical improvement related to this treatment.[18] In addition, it appears that there are substantial technical challenges and potentially severe adverse effects from this procedure. Therefore, Botox injections conducted as a diagnostic tool or for treatment of nTOS will not be authorized.

When feasible, job modifications that reduce the intensity of manual tasks may prevent progression and promote recovery from nTOS.[16] If symptoms persist despite appropriate treatment, permanent job modifications may still allow the patient to remain at work. Patients do not usually need time off from work activities prior to surgery, unless they present with objective weakness or sensory loss in the upper extremity that limits work activities or poses a substantial safety risk.

B. Surgical Treatment

Surgical treatment for nTOS has been described in narrative reviews, case reports, and retrospective case series.[4,19-34] Surgery should include exploration of the brachial plexus throughout its course in the thoracic outlet in order to decompress it by resecting any compressive and/or constrictive structures. These may include any of the three sites of compression mentioned earlier. No specific method of surgical treatment has been proven to be most effective.

Surgical treatment should only be considered if:

1. The patient has met the diagnostic criteria under Section III, and
2. The condition interferes with work or activities of daily living, and
3. The condition does not improve despite conservative treatment.

Without confirmation of nTOS **by both objective clinical findings and abnormal EDS**, surgery will not be authorized.

VI. Return to Work (RTW)

A. Early Assessment

Timeliness of the diagnosis can be a critical factor influencing RTW. Among workers with upper extremity disorders, 7% of workers account for 75% of the long-term disability.[35] A large prospective study in the Washington State workers' compensation system identified several important predictors of long-term disability: low expectations of return to work (RTW), no offer of a job accommodation, and

high physical demands on the job.[36] Identifying and attending to these risk factors when patients have not returned to work within 2-3 weeks of the initial clinical presentation may improve their chances of RTW.

Washington State workers diagnosed accurately and early were far more likely to RTW than workers whose conditions were diagnosed weeks or months later. Early coordination of care with improved timeliness and effective communication with the workplace is also likely to help prevent long-term disability.

A recent quality improvement project in Washington State has demonstrated that delivering medical care according to occupational health best practices similar to the quality indicators listed below can substantially prevent long-term disability. Findings can be viewed at: Centers of Occupational Health & Education.

B. Occupational Health Quality Indicators for Neurogenic Thoracic Outlet Syndrome (nTOS)

Clinical care action	Time-frame*
1. Identify physical stressors from both work and non-work activities; 2. Screen for presence of nTOS 3. Determine work-relatedness 4. Recommend ergonomic improvements or other appropriate job modifications	1st health care visit
Communicate with employer regarding return to work (RTW) using 1. Activity Prescription Form (or comparable RTW form) and/or 2. Phone call to employer	Each visit while work restrictions exist
1. Assess impediments for RTW 2. Request specialist consultation	If > 2 weeks of time-loss occurs or if there is no clinical improvement within 6 weeks of conservative treatment
Specialist consultation	Performed ASAP, within 3 weeks of request
Electrodiagnostic studies	If the diagnosis of nTOS is being considered, schedule studies immediately. These tests are required if time-loss extends beyond 2 weeks, or if surgery is requested.
Surgical decompression	Performed ASAP, within 4-6 weeks of determining need for surgery

*"Time-frame" is anchored in time from 1st provider visit related to nTOS symptoms.

C. Returning to Work Following Surgery

How soon a patient can return to work depends on the type of surgery performed and when rehabilitation begins. Most patients can return to light duty work within 4-6 weeks and regular duty within 10-12 weeks of surgery.

VII. Electrodiagnostic Worksheet

Claim Number: _____

Claimant Name: _____

PURPOSE AND INSTRUCTIONS

The purpose of this worksheet is to help interpret electrodiagnostic studies (EDS) done for an injured worker. The worksheet should be used only when the main purpose of the study is to evaluate neurogenic thoracic outlet syndrome (nTOS). It should accompany but not replace the detailed report normally submitted to the insurer.

Electrodiagnostic Worksheet for Work-Related Neurogenic Thoracic Outlet Syndrome (nTOS)

Electrodiagnostic criteria for Work-Related nTOS are met if all four boxes are "Yes".	**Check the correct box**	
	Yes	**No**
1. Ulnar SNAP* < 12 uV or absent? OR Medial antebrachial cutaneous nerve (MABC) SNAP* amplitude < 10 uV or absent, with normal amplitude of the MABC SNAP* in the contralateral (unaffected) extremity?		
AND		
2. Median nerve CMAP amplitude < 5 mV or absent? OR Ulnar F-wave (with or without abnormalities of the median F-wave) minimum latency > 33 msec or absent, with normal F-waves in the contralateral (unaffected) upper extremity? OR Needle electromyography (EMG) showing denervation (e.g. fibrillation potentials, positive sharp waves) in at least one muscle supplied by each of two different nerves from the lower trunk of the brachial plexus, with normal EMG of the cervical paraspinal muscles and at least one muscle supplied by a nerve from the middle or upper trunk of the brachial plexus?		
AND		
3. Normal amplitude (≥ 15uV) of the median nerve SNAP*?		
AND		
4. Normal conduction velocity (≥ 50 m/s) of the ulnar motor nerve across the elbow?		

*Antidromic

Additional Comments:

_____

_____

_____ _____

Signed Date

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Evidence was classified using criteria defined by the American Academy of Neurology[†]

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Appendix A – Guideline Supplement for Cervicobrachial Syndrome

This supplement to the neurogenic thoracic outlet syndrome (nTOS) guideline (10/1/2010) is intended to present: 1) New information that has bearing on the October 2010 guideline, and 2) Guidance on diagnosing and treating cervicobrachial syndrome, which can be confused with nTOS. Time limited treatment for cervicobrachial syndrome may be allowed when nTOS criteria are not met.

Update on the October 2010 nTOS Guideline

The Cochrane Collaborative published a recent review on the evidence for effective treatment of thoracic outlet syndrome.[1] The authors found very low or no quality evidence for the benefit of surgical interventions over non-treatment. They concluded that the review was "complicated by a lack of generally accepted diagnostic criteria for the diagnosis of TOS." Following the publication of the Cochrane review, vascular surgeons published reporting standards to gain some degree of consistency in reporting studies of disputed nTOS. However, these standards were meant as a guide for conducting future studies of nTOS, not definitive criteria to justify surgical intervention.[2]

When the insurer receives requests for surgery related to disputed nTOS, consideration includes absence of other reasonably likely diagnoses (cervical pathology, shoulder disease, carpal tunnel syndrome, chronic regional pain syndrome, brachial neuritis). This criterion is important in our workers' compensation system, as studies published to date in this population found that TOS was on average, the 10th diagnosis added on to a claim. The symptoms seen in nTOS are common in many diagnoses, and it is critical to perform a detailed neurological examination and adjunctive tests (e.g, MR neurography) to ensure accuracy prior to making a diagnosis of nTOS.

A recent two-part review [3, 4] provides criteria differentiating five types of TOS: arterial, venous, traumatic neurovascular, true neurogenic, and disputed neurogenic. This classification scheme is consistent with the criteria required under L&I's TOS guidelines. Further, these reviews characterize most cases of disputed TOS as a cervico-scapular pain syndrome rather than as a true type of TOS. In addition, a recent review of electrodiagnostic (EDS) features of true neurogenic TOS is consistent with criteria implemented in the 2010 L&I TOS guideline.[5] The importance of accurately identifying true neurogenic TOS and avoiding invasive surgery for disputed TOS is highlighted by L&I's research on outcomes of injured workers in WA, which demonstrated that the majority of workers who had surgery for purported nTOS had poor outcomes one year after surgery.[6, 7] Nearly 20% had new neurological complaints[7] and six injured workers suffered phrenic nerve injury, one with life threatening respiratory insufficiency [unpublished data]. Similarly, a case series from Brazil reported that 21 of 29 patients undergoing surgery for nTOS had not returned to work by 6 months post-op due to the presence of pain.[8]

Cervicobrachial Syndrome

Conditions that present with symptoms and signs that mimic those of nTOS, but that upon investigation do not demonstrate either objective neurologic or electrodiagnostic findings consistent with brachial plexus nerve injury are not addressed in the nTOS guideline.

This supplement addresses these conditions, which are described in ICD-10 M53.1 as cervicobrachial syndrome. For purposes of this guideline supplement, cervicobrachial syndrome includes conditions that present primarily with pain and muscle spasm in the cervical/brachial region, including predominant neck and often headache, sometimes accompanied by non-specific sensory symptoms in the affected distal upper extremity. These syndromes have no clearly demonstrable evidence of decreased reflexes, dermatomal sensory loss, specific muscle weakness and/or atrophy of the upper extremity, and no evidence of abnormal electrodiagnostic tests that corroborate the presence of objective brachial plexus involvement. Empirical data from work in normal volunteers and referred patients [9-13] led one author to conclude that, "The various neurologic conditions listed [Thoracic outlet syndrome, spinal cord tumors, nerve injuries, myelopathy, radiculopathy] are, by definition, not causes of neck pain. They cause symptoms, not in the neck, but in the upper limb. Furthermore, they cause loss of neurologic function rather than pain."[14]

Cervicobrachial syndrome may be treated with non-surgical treatments that are appropriate for the clinical presentation, including manual therapy, rehabilitation therapies, pain psychology, EMG biofeedback, and medication management. A systematic literature review of non-invasive therapies yielded 11 studies finding generally inconclusive evidence, though potential benefits were demonstrated for manual therapy, exercise, and behavioral therapy.[15] General physiotherapy and traction were found to be ineffective. Treatment of cervicobrachial syndrome requires a time-limited, goal-oriented multimodal treatment plan, ideally encompassing physical reactivation and treatment of psychosocial barriers.[16] Studies on more specific physical therapy techniques have also shown promise.[17] The primary goal of treatment should be functional improvement, with a secondary goal of improvement of pain. The provider should specify what the treatment plan is, how these goals will be measured, and the frequency with which they will report progress measurements to the insurer. Helpful resources have been produced by L&I for Functional Tracking and for treating Psychosocial Determinants Influence Recovery.

Botulinum Toxin Injections for Cervicobrachial Syndrome

Botulinum toxin A (BTX-A) injections have been shown to provide temporary reduction of pain intensity and increased pain tolerance in the neck and shoulder area.[18-22] Evidence suggests the injections are not curative, as the effects demonstrated are short-term (about 90 days).[18-22] As such, L&I considers the treatment temporarily rehabilitative.

In injured workers with signs and symptoms that do not demonstrate objective neurologic findings with corroborating electrodiagnostic results consistent with brachial plexus nerve injury, use of BTX-A may be considered to increase the ability of an injured worker to initiate and

complete a time-limited, goal oriented multimodal non-surgical treatment plan. The insurer may approve one course of BTX-A injections in the affected area. One additional course of injections may be authorized at least 90 days after the initial course in accordance with L&I coverage criteria.

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Definitions for Classification of Evidence

Rating of Therapeutic Article	Rating of Diagnostic Article	Rating of Prognostic Article	Rating of Screening Article
Class I: Prospective, randomized, controlled clinical trial with masked outcome assessment, in a representative population. The following are required: a) primary outcome(s) clearly defined b) exclusion/inclusion criteria clearly defined c) adequate accounting for drop-outs and cross-overs with numbers sufficiently low to have minimal potential for bias d) relevant baseline characteristics are presented and substantially equivalent among treatment groups or there is appropriate statistical adjustment for differences.	**Class I:** Evidence provided by a prospective study in a broad spectrum of persons with the suspected condition, using a reference (gold) standard for case definition, where test is applied in a blinded evaluation, and enabling the assessment of appropriate tests of diagnostic accuracy. All patients undergoing the diagnostic test have the presence or absence of the disease determined.	**Class I:** Evidence provided by a prospective study of a broad spectrum of persons who may be at risk for developing the outcome (e.g. target disease, work status). The study measures the predictive ability using an independent gold standard for case definition. The predictor is measured in an evaluation that is masked to clinical presentation and, the outcome is measured in an evaluation that is masked to the presence of the predictor. All patients have the predictor and outcome variables measured.	**Class I.** A statistical, population based sample of patients studied at a uniform point in time (usually early) during the course of the condition. All patients undergo the intervention of interest. The outcome, if not objective, is determined in an evaluation that is masked to the patients' clinical presentations.
Class II: Prospective matched group cohort study in a representative population with masked outcome assessment that meets a-d above OR a RCT in a representative population that lacks one criteria a-d.	**Class II:** Evidence provided by a prospective study of a narrow spectrum of persons with the suspected condition, or a well-designed retrospective study of a broad spectrum of persons with an established condition (by "gold standard") compared to a broad spectrum of controls, where test is applied in a blinded evaluation, and enabling the assessment of	**Class II:** Evidence provided by a prospective study of a narrow spectrum of persons at risk for having the condition, or by a retrospective study of a broad spectrum of persons with the condition compared to a broad spectrum of controls. The study measures the prognostic accuracy of the risk factor using an acceptable independent gold standard for case definition. The risk	**Class II.** A statistical, non-referral clinic-based sample of patients studied at a uniform point in time (usually early) during the course of the condition. Most patients undergo the intervention of interest. The outcome, if not objective, is determined in an evaluation that is masked to the patients' clinical presentation.

	appropriate tests of diagnostic accuracy.	factor is measured in an evaluation that is masked to the outcome.	
Class III: All other controlled trials (including well-defined natural history controls or patients serving as own controls) in a representative population, where outcome is independently assessed, or independently derived by objective outcome measurement.**	**Class III:** Evidence provided by a retrospective study where either persons with the established condition or controls are of a narrow spectrum, and where the reference standard, if not objective, is applied by someone other than the person that performed the test.	**Class III:** Evidence provided by a retrospective study where either the persons with the condition or the controls are of a narrow spectrum. The study measures the predictive ability using an acceptable independent gold standard for case definition. The outcome, if not objective, is determined by someone other than the person who measured the predictor.	**Class III.** A sample of patients studied during the course of the condition. Some patients undergo the intervention of interest. The outcome, if not objective, is determined in an evaluation by someone other than the treating physician.
Class IV: Evidence from uncontrolled studies, case series, case reports, or expert opinion.	**Class IV:** Any design where test is not applied in an independent evaluation OR evidence provided by expert opinion alone or in descriptive case series (without controls).	**Class IV:** Any design where the predictor is not applied in an independent evaluation OR evidence provided by expert opinion or case series without controls.	**Class IV.** Expert opinion, case reports or any study not meeting criteria for class I to III.

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