

# Prescriber's Guide to the CerviFit® Home Therapy System

Effective January 1, 2022



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## What is the CerviFit®?

Covered by workers comp and auto insurance, CerviFit® is a unique patented home neck strengthening and conditioning DME device for which there is no equivalent under the rules of substitution. The 10-week evidenced-based program provides the patient with a convenient and consistent home therapy that is scalable as the patient improves. The patient should be scheduled every two weeks by the appropriate medical staff to be seen as a follow-up on their therapy for a total of five visits and those interactions should be billed under the appropriate ICD-10 interaction code.

## How to prescribe:

1. Physician RX with the appropriate ICD-10 code see page 12 for script.
2. Physician notes including a statement of medical necessity (Example "I am prescribing the CerviFit for his/her constant neck pain as a result of (identify trauma ie, auto, work related, chronic, acute). Given the persistence of this, I will order the CerviFit reconditioning strengthening home program as it is medically necessary for the patient's rehabilitation").

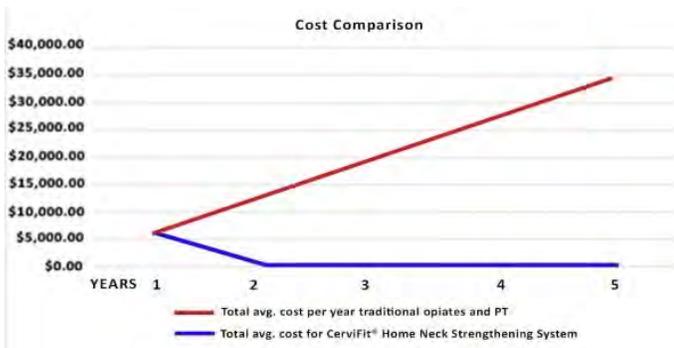
## Cost containment meets convenience:

Once you prescribe the CerviFit® home therapy system, you are part of an innovative shift in medicine. The CerviFit rehabilitation system has consistently demonstrated to the payors, the benefits of a compliant home-based therapy program.

The graph below illustrates savings calculated through CMS billing protocols for various cervical pathologies that the CerviFit had been prescribed for. These include, the combination of opioid, out-patient physical therapy (3x week/12 weeks) and anti-inflammatory therapies.

Why do we base the cost savings over the course of five years? Unlike traditional DME, the CerviFit device is the patients to own. Of the CerviFit patient population, 95% of the respondents have indicated that they still use the device to maintain their cervical health.

The CerviFit device comes with a two-year manufacturer's warranty. Physicians prescribing the CerviFit device advocate innovation and improvement in their patient's care by providing them the requisite tools to live a life free of pain.



This information is provided for your convenience only. It does not constitute legal advice or a recommendation regarding clinical practice. Information provided is gathered from third-party sources and is subject to change without notice due to frequently changing laws, rules, and regulations.

FOR QUESTIONS, PLEASE CONTACT US AT: [info@homelynx.health](mailto:info@homelynx.health)

## ICD-10-CM<sup>1</sup> Diagnosis Codes

Diagnosis codes are used by both physicians and hospitals to document the indication for the procedure.

CerviFit® home therapy system is directed at managing chronic and acute MSK pain. Pain can be coded and sequenced several ways depending on the nature of the encounter and the documentation. Pain codes from the G89 series are used as the principal diagnosis when the encounter is for pain control or pain management, rather than for management of the underlying condition. When a patient is prescribed CerviFit for the management of pain, the G89 pain code is sequenced as the principal diagnosis. Additional codes may then be assigned to identify the underlying cause and give more detail about the nature and location of the pain.

### Migraines

<b>G43.901</b>	Migraine, unspecified, not intractable, with status migrainosus
<b>G43.909</b>	Migraine, unspecified, not intractable, without status migrainosus

### Cervical Strain

<b>S16.1XXA</b>	Strain of muscle, fascia and tendon at neck level, initial encounter
<b>S16.1XXD</b>	Strain of muscle, fascia and tendon at neck level, subsequent encounter
<b>S16.1XXS</b>	Strain of muscle, fascia and tendon at neck level, sequela
<b>M54.2</b>	Cervicalgia

### Tension Headaches

<b>G44.201</b>	Tension-type headache, unspecified, intractable
<b>G44.209</b>	Tension-type headache, unspecified, not intractable

### Herniated Disc

<b>M50.10</b>	Cervical Disc disorder with radiculopathy unspecified region
<b>M50.11</b>	Cervical Disc disorder with radiculopathy High Cervical Region

**ICD-10-CM<sup>1</sup> Diagnosis Codes** continued

<b>Herniated Disc (Cont.)</b>	<b>M50.13</b>	Mid Cervical disc disorder unspecified region
	<b>M50.120</b>	Cervical disc disorder unspecified region
	<b>M50.121</b>	Cervical Disc disorder at C4-C5 level with radiculopathy
	<b>M50.122</b>	Cervical Disc disorder at C5-C6 level with radiculopathy
	<b>M50.123</b>	Cervical-Disc disorder at C6-C7 level with radiculopathy
<b>Whiplash Injury (Cervical Spine)</b>	<b>S13.4XXA</b>	Sprain of ligaments of cervical spine, initial encounter
	<b>S13.4XXD</b>	Sprain of ligaments of cervical spine, subsequent encounter
	<b>S13.4XXS</b>	Sprain of ligaments of cervical spine, sequela
<b>Neck Pain Unspecified Parts of the Neck</b>	<b>S13.9XXA</b>	Sprain of joints and ligaments of unspecified parts of neck, initial encounter
	<b>S13.9XXD</b>	Sprain of joints and ligaments of unspecified parts of neck, subsequent encounter
	<b>S13.9XXS</b>	Sprain of joints and ligaments of unspecified parts of neck, sequela
<b>Post Traumatic Neck Pain</b>	<b>G44.301</b>	Post traumatic headache, unspecified, intractable
	<b>G44.309</b>	Post-traumatic headache, unspecified, not intractable
	<b>G44.311</b>	Acute post-traumatic headache, not intractable
	<b>G44.319</b>	Unspecified mononeuropathy of unspesied lower limb
	<b>G44.321</b>	Chronic post-traumatic headache, intractable
	<b>G44.329</b>	Chronic post-traumatic headache, not intractable
<b>Occipital Neuralgia</b>	<b>M54.81</b>	Occipital neuralgia
<b>Radiculopathy</b>	<b>M50.10</b>	Cervical disc disorder with radiculopathy, unspecified cervical region
	<b>M50.11</b>	Cervical disc disorder with radiculopathy, high cervical region
	<b>M50.121</b>	Cervical disc disorder at C4-C5 level with radiculopathy
	<b>M50.122</b>	Cervical disc disorder at C5-C6 level with radiculopathy
	<b>M50.123</b>	Cervical disc disorder at C6-C7 level with radiculopathy
	<b>M50.13</b>	Cervical disc disorder with radiculopathy, cervicothoracic region
	<b>M51.14</b>	Intervertebral disc disorders with radiculopathy, thoracic region
	<b>M51.15</b>	Intervertebral disc disorders with radiculopathy, thoracolumbar region
	<b>M54.12</b>	Radiculopathy, cervical region
	<b>M54.13</b>	Radiculopathy, cervicothoracic region

## CerviFit® Home Strengthening and Reconditioning Program Study

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7/01/2020

People with work related injuries are the most difficult to treat and tend to have a less favorable outcome compared to the general population. There are several factors for this with the most obvious being patient motivation (or the lack thereof). Other contributing causes include time constraint, delay in initiating treatment, the quality/consistency of physical therapy, and poor coordination of care between providers and the third-party payors.

Neck and upper body pain, including headache and shoulder pain, represent a substantial number of those injured at work. Though the absolute number may not represent the highest percentage of those injured (20% approx.) based on a 2019 Zurich insurance study comprised of a formal analysis of more than 6,000 yearly worker injury claims in the healthcare industry. Representing about \$30 million in annual claim payments, (entitled The Benchmark Study of Healthcare Workers' Compensation Claims Statistics, it tends to be the most protracted in terms of treatment days and missed workdays. The cause for poor treatment outcome is the current treatment modalities are not designed to properly correct the underlying pathophysiological cause of the injury. Correlating this with the fact that 15% of all work-related injuries account for 85% of the costs, affirms that the CerviFit Home Program is both the medical treatment of choice and the financially prudent course of action for this patient type.

The CerviFit Strengthening and Reconditioning Program is unique in its design and treatment platform. By addressing the underlying fundamental cause of these pain types, it improves treatment outcome, motivates patient compliance, improves functionality, and is cost effective to the insurance carrier.

### Clinical Criteria for Entry:

All the enrolled WC patients were referred to the neurologist either by a WC PCP or a specialist (typically from an Orthopedist, occasionally the Pain Interventionist) after failing traditional conservative medical care such as physical therapy and medication. Those that were evaluated by at least one specialist prior to the neurological referral had additional treatments such as a change in medications, renewal of therapy, and/or invasive procedures such as cervical epidurals or shoulder injections. Interestingly, none of the patients were seen in the acute phase of the injury, i.e., not before 3 months post event.

The breakdown of patients:

- 24 Males, 20 Females
- Male Population (Yrs. old) 30% (18-32), 60% (33-47), 10% (50-65)
- Female Population (Yrs. old) 35% (18-32) 55% (33-49) 10% (49-72)

Though the chief complaints were neck and upper body pain, there were associated pain symptoms in their shoulder(s) and head and sensory complaints in the extremity(ies). Over three quarters had radicular symptoms at the onset of their injuries (sensory loss, pain, weakness) into one or both upper extremities. The most common reason for the referral from the treating physician to the neurologist was for the diagnosis of headaches. Other diagnoses were neck pain, radiculopathy, and/or vertigo. Any combination of these symptoms, with an abnormal examination were considered appropriate candidates for the CerviFit Home program.

The examination had to demonstrate a decrease in the ROM of the cervical spine by more than 15 degrees in at least 2 out of the 4 planes (typically there were restricted movements in all four movements to varying degrees). Other findings included asymmetrical weakness of the neck muscles, decreased ROM of one or both shoulders, multiple trigger points bilaterally, and neurological deficits (such as radiculopathy, entrapment brachial plexopathies, CTS, dystonia, occipital neuralgia).

Objective Testing:

Once approved for the CerviFit Home Program, each patient's baseline tensile neck strength was measured by a handheld dynamometer (pounds per square inches) with a custom designed head strap.

The neck movements recorded were:

1. Flexion
2. Extension
3. Left lateral extension
4. Right lateral extension

Part of the initial evaluation with the CerviFit Home Program included rating their pain via the VAS (Visual Analog Scale) and their functional limitations based on the Oswestry Neck Disability Index (see the attached questionnaire).

Of note, all patients had an MRI of the Cervical spine prior to starting the CerviFit Program, but the specific pathology on the imaging study was not tabulated with the other indicators, nor were any neuroimaging parameters established. However, any

type of cervical spinal fracture, spinal cord compression, or recent cervical surgery were excluded. The caveat with the latter is the patients with preexisting spinal surgeries were not considered absolute contraindications. If these patients already had physical therapy during their course of treatment, then they were eligible for the CerviFit Program. Those who had surgery subsequent to the CerviFit program, resumed the program once they were cleared by the surgeon to initiate post op physical therapy.

Electro-diagnostic studies were performed on two thirds of those enrolled, (several had this study performed at an outside facility prior to the referral). The findings varied from negative to cervical radiculopathy. These results were not used as a criterion for the CerviFit Home Reconditioning and Strengthening Program so no determination could be made about the effectiveness of the program regarding the neuropathic abnormalities.

#### Clinical Data:

Over the course of the 10 Week program, the patients were evaluated in the office every two weeks. In addition to the standard clinical evaluation, the physician utilized the VAS for pain, the Oswestry Disability Neck Index, and the dynamometer.

Of the 44 patients, 86% or (38) were compliant with the 10-week treatment program. Two (2) patients had missed or failed to show-up for their follow-up clinical evaluation on a consistent basis, thus rendering them non-compliant. Three had inconsistent results (in conjunction with other clinical factors) and were deemed malingerers. One discontinued use of the program to undergo Chemotherapy for Breast Cancer. One discontinued, to undergo cervical arthroplasty, but restarted the program in the post-acute phase of their rehabilitation.

- 30% of the patients had one or more level disc protrusion as a result of the injury
- 35% had preexisting chronic pathological changes in the cervical spine or in the shoulder
- 64% of the patient population studied had cervicogenic headaches and 5% had exacerbations of preexisting migraines
- 52% had shoulder pain, typically diagnosed with impingement syndrome.
- All had asymmetric weakness of the cervical neck muscles with weakness in all planes of movement per the dynamometer.

Of those patients who were compliant with the program, all had improvement clinically. Their overall cervicogenic pain improved based on their VAS (Visual Analog Scale) and improved functionality per the Oswestry Index.

#### Clinical Results At The End Of The Program:

- Overall, there was a 28% improvement in tensile strength in the compliant patients with 57% (25 people) experiencing an average 40% improvement.
- The average reduction on the Oswestry Index Scale was 8 points with 70% converted from moderate to mild disability.
- The VAS was decreased from 7 to 3.5 on average, though the maximum pain during an exacerbation was reduced by 2 points in the majority of patients.
- All the compliant patients continued to use the CerviFit device at the completion of the study. Most stayed at the 1-to-2-pound weights.
- There were no injuries or complications with the device. Initially a few had recurrence of their pain as they did not understand the principle, technique, or follow the proper exercise instructions of the program.

Conclusion:

All the enrolled patients in the CerviFit Program had been refractory to the standard treatment currently practiced by the medical community in the Workman's Compensation arena. The number of patients who had a positive response, and their success rate, was higher than anticipated. The reason for this was multi-factorial. The patients had input and control in their care, received tangible feedback every two weeks over the course of the program, and expressed improved quality of life as documented by the Oswestry Index scale.

Additionally, Workman's Compensation insurance carriers have the ability to discharge a patient if noncompliance is documented. The physician was able to confirm noncompliance in four patients and all treatment was immediately terminated.

A larger study is needed to determine what factors influence clinical outcome such as underlining pathology, job description and time of onset to treatment with the overall goals of reducing the number of medications such as opiates, and the recurrence rate of exacerbations. Other diagnostic tests such as electrodiagnostic studies, X rays, and neuroimages and neuropsychological evaluations need to be included to determine which abnormalities are predictors of outcome and functionality.

CerviFit Device



Dynamometer



Dr. Jeffrey Steinberg is a Board-Certified Neurologist with over 25 years of clinical experience. Dr. Steinberg completed his residency at Kaiser Permanente Los Angeles University of California, Davis, an Interventional Pain Fellowship at University of Louisville, (Veterans Administration) and Neurophysiology/Sleep Fellowship at Emory University. Dr. Steinberg is the Founder of the Headache and Pain Center of South Florida with a focus on Patient-Centric Care.

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# SAMPLE NECK Pain and Disability Questionnaire

Rate the severity of your pain by circling one number: (No Pain) 0...1...2...3...4...5...6...7...8...9...10 (Excruciating Pain)

This questionnaire has been designed to give the doctor information as to how your neck pain has affected your ability to manage everyday life. Read through each section and check only ONE line that applies to you. You may find that two of the statements in a section relate to you, but please just check ONE line that best describes your current predicament.

## Section 1– Pain Intensity

- I have no pain at the moment.
- The pain is very mild at the moment.
- The pain is moderate at the moment.
- The pain is fairly severe at the moment.
- The pain is very severe at the moment.
- The pain is the worst imaginable at the moment.

## Section 2– Personal Care (washing, dressing, etc.)

- I can look after myself normally without causing extra pain.
- I can look after myself normally but it causes extra pain.
- I am slow and careful because it is painful for me to look after myself.
- I need some help but manage most of my personal care.
- I need help every day in most aspects of care.
- I do not get dressed, I wash with difficulty and stay in bed.

## Section 3– Lifting

- I can lift heavy weight without extra pain.
- I can lift heavy weight but it causes extra pain.
- I cannot lift heavy weight off the floor, but I can manage if they are conveniently positioned like on a table.
- I cannot lift heavy weight, but I can manage light to medium weights if they are conveniently positioned.
- I cannot lift any weight due to neck pain.

## Section 4– Reading

- I can read as much as I want to with no pain in my neck.
- I can read as much as I want to with slight neck pain.
- I can read as much as I want to with moderate neck pain.
- I cannot read as much as I want to due to moderate neck pain.
- I can hardly read at all because of severe neck pain.

## Section 5– Headaches

- I have no headaches at all.
- I have slight headaches that occur infrequently.
- I have moderate headaches that occur infrequently.
- I have frequent moderate headaches.
- I have frequent severe headaches.
- I have severe headaches all the time.

## Section 6- Concentration

- I can concentrate fully when I want to with no difficulty.
- I can concentrate fully when I want to with slight difficulty.
- I have a fair degree of difficulty in concentrating when I want to.
- I have a great deal of difficulty in concentrating when I want to.
- I cannot concentrate at all.

## Section 7- Work

- I can do as much work as I want to.
- I can only do my usual work, but no more.
- I can do most of my usual work, but no more.
- I cannot do my usual work.
- I can barely do any work at all.
- I cannot do any work at all.

## Section 8- Driving

- I can drive my car without any neck pain.
- I can drive my car as long as I want with slight neck pain.
- I can drive my car as long as I want with moderate neck pain.
- I cannot drive my car as long as I want.
- I can hardly drive at all because of severe neck pain.
- I cannot drive my car at all.

## Section 9- Sleeping

- I have no trouble sleeping.
- My sleep is slightly disturbed (less than 1 hour sleepless)
- My sleep is mildly disturbed (1 hour sleepless)
- My sleep is moderately disturbed (2 to 3 hours sleepless)
- My sleep is greatly disturbed (4 to 5 hours sleepless)
- My sleep is completely disturbed (6 to 7 hours sleepless)

## Section 10- Recreation

- I am able to engage in all my recreation activities with no neck pain.
- I am able to engage in all my recreation activities with some neck pain.
- I am able to engage in most, but not all of my usual recreation activities.
- I am able to engage in a few of my usual recreation activities.
- I can hardly do any recreation activities.
- I cannot do any recreation activities due to neck pain.

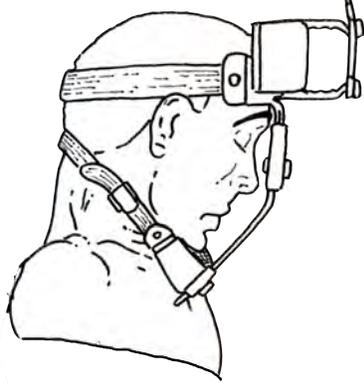
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Patient Name (Print)

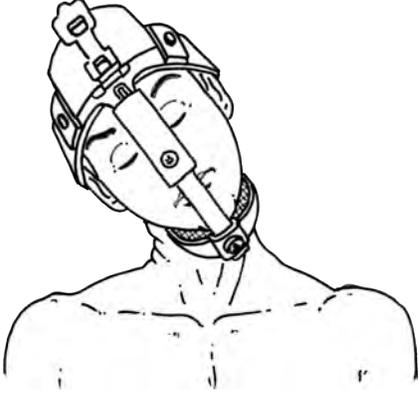
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Patient Signature

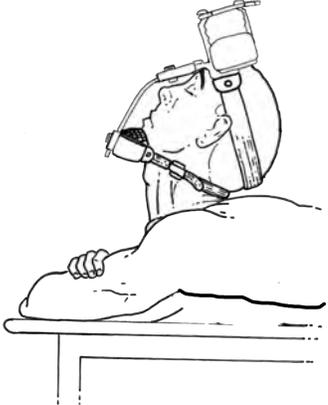
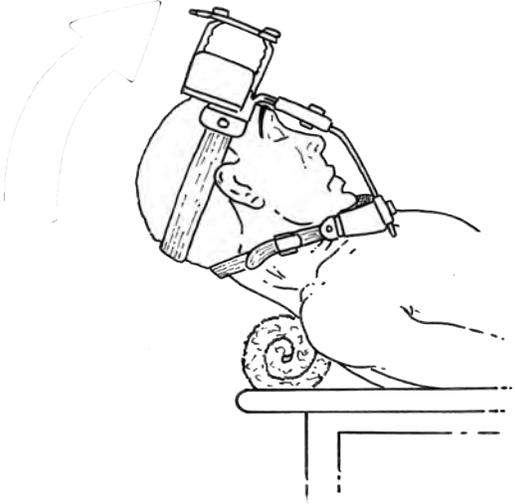
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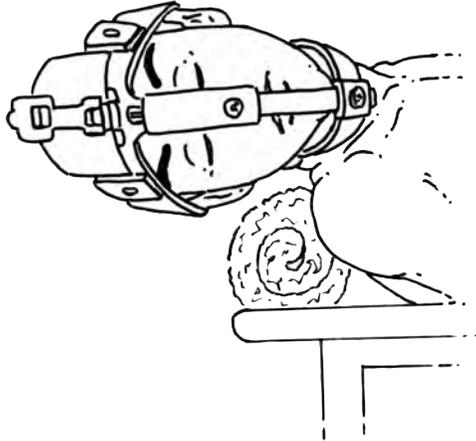
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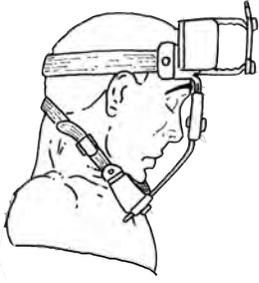
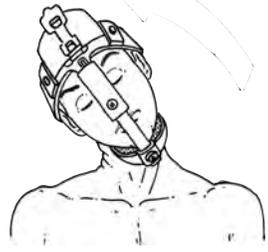
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Total Points                      x 2 =                      \_\_\_\_\_  
Disability Percentage                      Rating Scale

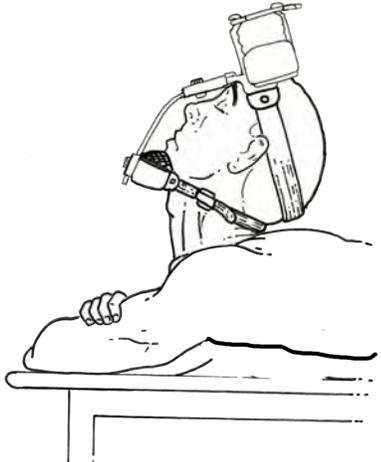
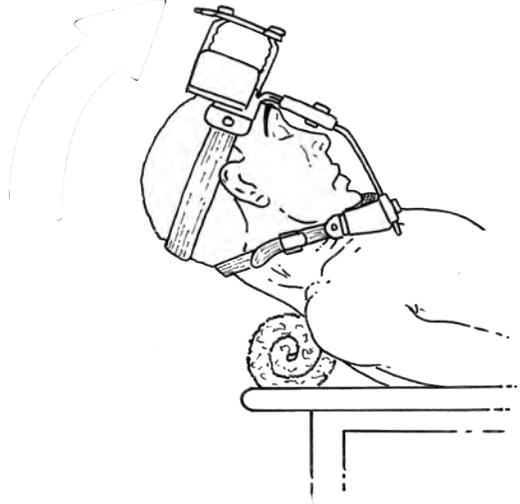
Acute Phase 1 home therapy exercises					
Injury	Exercise Type	Sets	Times Per Week	Repetitions	Pictorial Reference
Cervicalgia (Posterior/Rear)	Stretching	3	5	20-30 second static stretching.	 <p>Sitting upright in a chair with firm back support, allow the weight to pull your head toward your chest. With your head down and stretching, turn your head toward your opposite side of your chest. This will also release some pressure on the spinal facets.</p>
Cervicalgia (Anterior/Front)	Stretching	3	5	20-30 second static stretching	 <p>Sitting upright in a chair with firm back support, allow the head to stretch back ensuring to stretch only within your comfort. With your head back slowly bring your ear toward your shoulder, then back to center repeat on the other side. *If one part of your neck feels tighter then the other, try to spend some additional time stretching that side.</p>

Cervicalgia (Sagittal/Side)	Stretching	3	5	20-30 second Static stretching	 <p>Sitting upright in a chair with firm back support, bring your ear to your shoulder allowing the weight of the device to stretch the side of your neck. When comfortable, lower the opposite shoulder gradually increasing the stretch. Repeat on the other side.</p> <p>Sitting upright in a chair with firm back support, bring your ear to your shoulder allowing the weight of the device to stretch the side of your neck. When comfortable, lower the opposite shoulder gradually increasing the stretch. Repeat on the other side.</p>
Intermediate Phase 2 home therapy exercises					
<b>Injury</b>	<b>Exercise Type</b>	<b>Sets/Reps</b>	<b>Times Per Week</b>	<b>Pictorial Reference</b>	

Cervicalgia (Posterior)	Extension	3/10	4	 <p>Lying flat on a raised surface, allowing the head to slowly rise and fall. When bringing your head down, try to round your neck stretching the back of the disks (facets)</p>
Cervicalgia Front (Anterior)	Flexion	3/10	4	 <p>Lying flat on a raised surface, allowing the head to slowly rise and fall. Stop an inch or two from the chest. Repeat. <b>Goal:</b> Slow and deliberate movement focusing on range of motion and stretching</p>

<p>Cervicalgia Side (Sagittal)</p>	<p>Rotation</p>	<p>3/10</p>	<p>4</p>	 <p>Lying flat on a raised surface, lifting the head till it is parallel to your shoulders. Slowly turn the head to the left, back to center then to the right. Each time returning to center with a 2 second hold. <b>Goal:</b> To strengthen the muscles on the side of the neck which facilitate rotation.</p>
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Acute Phase 1 home therapy exercises					
Injury	Exercise Type	Sets	Times Per Week	Repetitions	Pictorial Reference
Whiplash (Posterior/Rear)	Stretching	3	5	20-30 second static stretching.	 <p>Sitting upright in a chair with firm back support, allow the weight to pull your head toward your chest.</p>
Whiplash (Anterior/Front)	Stretching	3	5	20-30 second static stretching	 <p>Sitting upright in a chair with firm back support, allow the head to stretch back ensuring to stretch only within your comfort.</p>
Whiplash (Sagittal/Side)	Stretching	3	5	20-30 second Static stretching	 <p>Sitting upright in a chair with firm back support, bring your ear to your shoulder allowing the weight of the device to stretch the side of your neck. When comfortable, lower the opposite shoulder gradually increasing the stretch. Repeat on the other side.</p>

Intermediate Phase 2 home therapy exercises				
Injury	Exercise Type	Sets/Reps	Times Per Week	Pictorial Reference
Whiplash (Posterior)	Extension	3/10	4	 <p>Lying flat on a raised surface, allowing the head to slowly rise and fall. <b>Goal:</b> Slow and deliberate movement focusing on range of motion and stretching</p>
Whiplash (Anterior)	Flexion	3/10	4	 <p>Lying flat on a raised surface, allowing the head to slowly rise and fall. Stop an inch or two from the chest. Repeat. <b>Goal:</b> Slow and deliberate movement focusing on range of motion and stretching</p>

<p>Whiplash (Side/Sagittal)</p>	<p>Rotation</p>	<p>3/10</p>	<p>4</p>	<div data-bbox="1068 394 1546 835" data-label="Image"> </div> <p>Lying flat on a raised surface, lifting the head till it is parallel to your shoulders. Slowly turn the head to the left, back to center then to the right. Each time returning to center with a 2 second hold.  <b>Goal:</b> To strengthen the muscles on the side of the neck which facilitate rotation.</p>
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**Prescriber's Prescription \*\*Do Not Substitute\*\***

Please complete the information below and fax this form along with notes related to the relevant medical history & treatment to: Darah Medical 855-570-8782

**Patient Information**

Patient Name \_\_\_\_\_ Date of Birth \_\_\_\_\_ SS# \_\_\_\_\_

Patient Address \_\_\_\_\_

City \_\_\_\_\_ State \_\_\_\_\_ Zip Code \_\_\_\_\_ Phone \_\_\_\_\_

Case Type: Workers Comp Auto Insurance Provider: \_\_\_\_\_ Claim#: \_\_\_\_\_

Address: \_\_\_\_\_ Adjuster: \_\_\_\_\_ Phone Number: \_\_\_\_\_

**Diagnosis and Related Info**

Diagnosis \_\_\_\_\_ Date of Incident \_\_\_\_\_ ICD 10 Code \_\_\_\_\_

Symptoms \_\_\_\_\_

Limitations \_\_\_\_\_

**Pain Level:** No Pain Mild Pain Moderate Pain Severe Pain

**Product:** CerviFit® Home Cervical Rehabilitation System- Device, weights and instructions

I am prescribing CerviFit® an evidenced-based, home neck strengthening treatment program to reduce pain and accelerate the natural healing cascade for cervical musculoskeletal related injuries. CerviFit® has been shown in internal studies to improve ROM (Range of Motion), tensile neck strength and vertebral alignment.

**Prescriber Information**

Prescriber's Signature \_\_\_\_\_ Date \_\_\_\_\_

Prescriber's Printed Name \_\_\_\_\_ Prescriber's Address \_\_\_\_\_

City \_\_\_\_\_ State \_\_\_\_\_ Zip Code \_\_\_\_\_ Phone \_\_\_\_\_

NPI# \_\_\_\_\_ License# \_\_\_\_\_

**Note:** Please include with this script all the appropriate medical notes.

**Letter of Medical Necessity (LMN):** CerviFit® is medically necessary for the treatment of the patient's aforementioned pathology for home reconditioning to mitigate any exacerbation and patient discomfort.

Further, I am prescribing the CerviFit home strengthening and reconditioning system in lieu of a facility based intermittent program. With the objective of improving the underlying medical conditions, the CerviFit has in internal studies with patient's with similar pathologies, shown improvement. I am not prescribing this program with the device for personal comfort or convenience. I have determined, based on my medical expertise and judgment, that the Cervifit Program and device, is the best course of daily treatment for my patient.



**HomeLynxHealth, Inc.**

8950 SW 74 Ct.

Suite 2201 PMB D9

Miami, FL 33156

1-833-HomeLynx (466-3596)

[Info@homelynx.health](mailto:Info@homelynx.health)

[www.homelynx.health](http://www.homelynx.health)