**Fulcrum Health, Inc.**

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| **Policy Title:** | **Therapeutic Treatment Policy** | | |
| **Policy Number:** | CLINUM100 | **Effective Date:** | 6/1/2018 |
| | | **Last Revision Date:** | 03/12/2020 |
| | | **Last Review Date:** | 03/31/2020 |
| **Responsible Area/Individual:** | UM Program Director | | |
| **Purpose:** | This policy was written to provide a consistent determination of medical necessity in the review and management of neuromusculoskeletal disorders. | | |
| **Regulation/ Reference (if applicable):** | • Policy NM007 Non-Covered Services<br>• Policy UM004 Adoption of Clinical Guidelines<br>• Policy UM006 Data Elements for UM Clinical Determinations<br>• Policy CLINUM116 Definition and Application of Complicating Factors in the Utilization Management Process<br>• NCQA UM2 (2019) | | |

**Purpose:**

This policy applies to all programs where utilization review determinations about medical necessity are rendered. This policy also describes the current evidence-basis for the determination of maximum therapeutic benefit (MTB) in the management of neuromusculoskeletal disorders. Additionally, this policy acknowledges individual health care provider accountabilities in assessing for MTB and appropriate clinical decision-making once MTB has been reached.

**Policy:**

Review of treatment plans and service recommendations are performed by a Qualified Health Professional. Decision-making is based on criteria that is objective, patient specific, and dependent on best practice treatment standards that are nationally recognized clinical practice guidelines as well as regional peer set standards of care. Initial and ongoing treatment plans and service recommendations must be patient-focused and rely on relevant clinical data elements such as (including but not limited to): diagnosis, age, gender, activity limitations, comorbidities, complications, progress of treatment, psychosocial situations, home environment when applicable, and barriers to recovery. Ongoing care and medical necessity decisions are determined following a course of care, where demonstrable meaningful clinical improvement would be expected in a patient's health status.

Maximum Therapeutic Benefit (MTB) is determined when one or more of the following are present:

A. The patient has returned to pre-clinical/pre-onset health status.

B. Meaningful improvement may have occurred; however, documentation does not support that further meaningful gains will be achieved.

C. Meaningful improvement has occurred; however, documentation does not support further supervised ‘in-office’ treatment.

D. The patient no longer demonstrates meaningful clinical improvement or progress as measured by subjective or objective gains and/or standardized outcome assessment tools (i.e., neck and/or back indexes).
E. Meaningful improvement has not been achieved, as measured by standardized outcome assessment tools or documented in clinical records.
F. There is insufficient information (measurable subjective, objective, or functional changes) documented in the patient health care record to reliably validate the response to treatment.

## Definitions:

**Patient Classification:** Classification of the appropriate level of care is dependent upon the presenting symptomatology and medical history. Each category is distinct and provides specific parameters for the duration of treatment based on presenting clinical evidence. Categories:

A. Acute = symptom onset within 6 weeks of office presentation
B. Subacute = symptom onset within 6 to 12 weeks of office presentation
C. Chronic = symptoms present for 12 weeks or greater prior to office presentation

**Complications:** Individual Influences may delay recovery and must be considered in the total management of neuromusculoskeletal conditions: (factors include but not limited to)

Heredity, gender, age, body build, physical fitness, smoking, social class, symptom duration, prior history, heavy manual work, symptomatic herniated disc, scoliosis, disc degeneration, spondylosis, spondylolisthesis, spina bifida and transitional vertebrae

**Episode of Care:** Consultation or treatment preceded and followed by at least 3 months without treatment for the same complaint.

**Flare-ups/Exacerbations:** Phases of increased pain related to specific incidents superimposed on a recurrent or chronic course. A flare-up or exacerbation is characterized by a return of atypical pain and/or other symptoms and/or pain-related difficulty performing tasks and actions equivalent to the appropriate meaningful clinical change value.

**Maintenance Care:** Includes services that seek to prevent disease, promote health and prolong and enhance the quality of life, or maintain or prevent deterioration of a chronic condition. When further clinical improvement cannot reasonably be expected from continuous ongoing care, and the chiropractic treatment becomes supportive rather than corrective in nature, the treatment is then considered maintenance therapy.

**Maximum Therapeutic Benefit (MTB):** May be determined following a sufficient course of care where no further demonstrable meaningful clinical improvement would be expected in a patient's health status from the current method of treatment. Treatment beyond MTB may be considered maintenance care.

**Medical Necessity (MN Medicaid):** (pursuant to Minnesota Rules, Part 9505.0175, subpart 25) a health service that is: 1) consistent with the Enrollee's diagnosis or condition; 2) recognized as the prevailing standard or current practice by the Provider's peer group; and 3) rendered:

A. In response to a life-threatening condition or pain;
B. To treat an injury, illness or infection;
C. To treat a condition that could result in physical or mental disability;

D. To care for the mother and unborn child through the maternity period;
E. To achieve a level of physical or mental function consistent with prevailing community standards for diagnosis or condition; or
F. As a preventive health service.

**Medical Necessity:** Diagnostic testing and medical treatment, consistent with the diagnosis of and prescribed course of treatment for a condition, and preventative services. Medically necessary care must meet the following criteria:

A. Be consistent with the medical standards and accepted practice parameters of the community as determined by health care providers in the same or similar general specialty as typically manages the condition, procedure, or treatment at issue; and
B. Be an appropriate service, in terms of type, frequency, level, setting, and duration, to the diagnosis or condition; and
C. Help to restore or maintain health;
D. Prevent deterioration of a condition; or
E. Prevent the reasonably likely onset of a health problem or detect an incipient problem.

Note: The definition of "medically necessary" in the member's benefit contract may vary from the above definition. If the definitions are different, the definition in the member's plan document will prevail.

**Meaningful Improvement:** The minimum subjective, objective, or outcome assessment tool (OAT) improvement in the patient's status that is perceived as beneficial.

**Organization Determination**: A review determination made by a qualified health professional applying the maximum therapeutic benefit (MTB) review criteria at the request of a network practitioner who believes that his/her patient has achieved MTB and would like to precede with a self-pay agreement. The review and determination response to the provider and patient will follow the normal review and response process.

**Qualified Health Professional:** The Clinical Peer Reviewer with an unrestricted license in the same specialty area as the treating provider who is responsible for utilization management oversight, including reviewing treatment notes, making clinical decisions on treatment appropriateness and necessity, and focusing on peer-to-peer education.

**Recurrent Pain:** Pain that is present on less than half the days in a 12-month period occurring in multiple episodes. An episode of recurrence is characterized by a return of atypical pain and/or other symptoms and/or pain-related difficulty performing tasks and actions equivalent to the appropriate meaningful clinical change value for a minimum duration of 24 hours e.g., change in numeric rating scale of $\geq$ 2 points for chronic LBP.

**Outcome Assessment Tools:** Standardized self-reported patient questionnaires (i.e. Oswestry, Neck Disability Index).

## Overview:

Review of valid and reliable outcome assessment tools is required for assessment of initial and ongoing treatment. Assessment tools for the management of neuromusculoskeletal disorders are a core component of clinical management and considered "Best Practice. "Patient progress should be identified within the first 2-weeks of a treatment trial. If no progress is reported, the treatment approach should be modified, or a referral should be considered. Examples of clinically meaningful change:

A. Recovery patterns for typical acute neuromusculoskeletal conditions generally show clinically meaningful change (e.g., >50% of the overall improvement for spine-related disorders) is obtained within 4 – 6 weeks of the initial visit and should resolve within 90 days.
B. Meaningful improvement may be identified through subjective, objective, and OAT measures.
    a. **Subjective**:
        i. 2 pt. change in subjective pain when pain is ≥5/10
        ii. 1 pt. change in subjective pain when pain is ≤4/10
    b. **Objective or ADL**:
        i. Overall relative progress is at least 30% (e.g., ROM or specific ADL disturbance).
    c. **Functional Outcome Assessment**:
C. OAT= 10% raw score improvement
    - State specific Local Coverage Determinations (LCD's) will be utilized for the clinical review process of Medicare Recipients.

## Reported Clinical Information:

**QHP reviewers will assess patient and provider reported clinical information. This information may be reported by:**

A. Daily clinical records notes
B. Fulcrum developed authorization forms and/or assessments
C. Standardized outcome assessment tools (i.e. Revised Oswestry, Neck Disability Index)
D. Prior clinical reviewer notes
E. Other requested documentations

## Tables

The following tables are used to facilitate and guide the review of treatment plans and service recommendations performed by Qualified Health Professional.

Table 1. a. Initial Course of Care

Table 1. b. Ongoing treatment recommendation/support

Table 1. c. Flare-ups/ Exacerbations

Table 2. Decision Elements for Ongoing treatment recommendation/support

Table 1. a.

| Therapeutic Treatment Policy | | | | |
|---|---|---|---|---|
| **Case Type:** | **Uncomplicated** | **Complicated** | **Moderate** | **Severe** |
| **Acute (4-8 weeks for initial course of care)** | **Not to exceed 8 visits** | **Not to exceed 12 visits** | **Not to exceed 16 visits** | **Not to exceed 20** |

Table 1. b.

| **Therapeutic Treatment Policy** | | | | | |
|---|---|---|---|---|---|
| | 1 | 2 | 3 | 4 | 5 |
| | **Uncomplicated Progress Stalled** | **Uncomplicated - near MTB** | **Complicated - Moderate** | **Complicated - Severe** | **Complicated not improving** |
| **Sub-Acute Care (4-8 weeks for ongoing care)** | Ongoing care not supported<br>Plateau or MTB | Low visit ongoing care supported | Medium visit ongoing care supported | High visit ongoing care supported | Referral Recommendation |
| **Visit recommendation supported by provider and patient-specific clinical information:** | None | Not to exceed 3 visits | * Not to exceed 6 visits | * Not to exceed 9 visits | 2 visits for referral |
| *** Complication Attribute Visits** | Add (0-2) | Add (0-2) | Add (0-4) | Add (0-6) | N/A |

* Provider reported patient attributes for consideration: Anxiety, BMI>40, Cancer, Depression, Diabetes, Inflammatory Arthritis, Multiple Episodes, Osteoporosis, Physical Lifestyle, Post-Surgical, Pregnancy, Prescriptions, Smoker, Sedentary Lifestyle, Occupational, Behavioral Issues, Age, , Progress of Treatment, Psychosocial Situation, Home Environment When Applicable, and other applicable complications and/or comorbidities.

Table 1. c.

| **Therapeutic Treatment Policy** | | | |
|---|---|---|---|
| **Case Type:** | **Uncomplicated** | **Complicated** | **Complicated Severe** |
| **Flare-ups/Exacerbations (should include withdrawal from care of greater than 60 days)** | **Not to exceed 4 visits** | **Not to exceed 8 visits** | **Not to exceed 12 visits** |

Table 2.

| Decision Elements: Need 4 of 7 | | | | | |
|---|---|---|---|---|---|
| **Decision Element** | 1 | 2 | 3 | 4 | 5 |
| **i. Silver assessment (previous visit amount, response to care)** | Treatment has exceeded previous visit approval or waiver | Treatment has exceeded previous visit approval or waiver | Treatment has exceeded previous visit approval or waiver | Treatment has exceeded previous visit approval or waiver | Treatment has exceeded previous visit approval or waiver |
| **ii. Neurologic Complications** | No radiculopathy<br>Reflexes normal | No radiculopathy<br>Reflexes normal | Radiculopathy (Improvement noted)<br>Reflexes (improved) | Radiculopathy (Improvement noted)<br>Reflexes (improved) | Radiculopathy (no improvement)<br>Reflex (no improvement) |
| **iii. Provider and/or Patient reported Complaint-Specific Data** | Continued issues with pain without lasting meaningful change (previous 60 days)<br>Frequent exacerbations despite care. No attempted withdrawal from care | Low pain levels (less than 4/10). Low pain frequency<br>Significant pain relief | Moderate pain (3-7 / 10)<br>Moderate to signification pain relief. Greater than 25% improvement | Moderate to high pain (5-10/10). Greater than 25% improvement | Increasing pain levels or pain levels unchanging |
| **iv. Individual ADL's reported in OAT (Outcome Assessments)** | Individual ADL's improvement not sustained for three months | Minimal disability score per activity question (0-1) | Moderate disability score per activity question (1-2) | Improving ADL scores over 25% improvement, but still trouble performing.<br>Disability per activity (2-4) | No ADL improvement or worsening scores for the same episode |
| **v. Disability level- Total OATs Scores** | Exacerbations that show little to no lasting stability OAT score less than 20% on an ongoing basis | Minimal Disability Scores<br>OAT score less than 20% | Minimal to Moderate Disability Scores (20 - 40% disability) * | Moderate to Severe Disability but improving Scores (40-80 %disability) *<br>Greater than 80% may require further inquiry | No change or worsening total scores (Exacerbations that cause scores to be as bad as original with extensive care already given) |
| **vi. Change interval noticeable in OATs (If available two assessments available)** | No Meaningful improvement from care is documented | Meaningful improvement from care is documented | Slight to moderate improvement, but not to low level need | Significant improvement with care but high ADLs still evident | Care showing no change in member condition |
| **vii. Previous communication** | Web note or Response language indicating MTB expected with this treatment extension | Web note or Response language indicating MTB expected with this treatment extension | Web note or Response language indicating MTB expected with this treatment extension | Web note or Response language indicating MTB expected with this treatment extension | Web note or Response language indicating MTB expected with this treatment extension |

* Provider reported patient attributes for consideration: Anxiety, BMI>40, Cancer, Depression, Diabetes, Inflammatory Arthritis, Multiple Episodes, Osteoporosis, Physical Lifestyle, Post-Surgical, Pregnancy, Prescriptions, Smoker, Sedentary Lifestyle, Occupational, Behavioral Issues, Age, , Progress of Treatment, Psychosocial Situation, Home Environment When Applicable, and other applicable complications and/or comorbidities.

**Process:**

**Use of Clinical Algorithms** Health care algorithms are designed to assist clinicians by providing an objective analytical framework for the assessment of the treatment request based on the response to care for spine-related musculoskeletal complaints.

## A. Acute Musculoskeletal Algorithm

A. Initial clinical trial, up to sixty days.
B. Within the initial clinical trial there must be resolution of the condition or greater than 25% improvement.
   **a.** Measured by:
   **b.** Assessment of the patient indicates significant (25-50%) relief of pain and/or progress towards premorbid function. Information must be relevant (recent and timely) for comparisons.
      - Patient reported assessment of pain e.g. numerical scale.
      - Patient reported disability measures e.g., Back and/or Neck Index; Oswestry –
   **c.** Continuation of care is supported (see Sub-Acute Algorithm)
   **d.** If continuation of care is not supported, see table 1.b. for transition message.

## B. Sub-Acute Musculoskeletal Algorithm

A. Progress with care plan support up to an additional 60 days based on documented progress through recent (how old) (list assessments you need to evaluate care"
   a. Measured by:
   b. Assessment of the patient indicates significant (25-50%) relief of pain and/or progress towards premorbid function. Information must be relevant (recent and timely) for comparisons.
      - Patient reported assessment of pain e.g. numerical scale.
      - Patient reported disability measures e.g., Back and/or Neck Index; Oswestry –
   c. Continuation of care is supported refer to table 1.b for recommendation.
   d. Lack of significant improvement in the outcome assessment data following a maximum of three consecutive evaluations during which the treatment approach has been modified and complicating factors have been considered does not support a continuation of treatment. see table 1.b for transition message.

## C. Flare-up/Exacerbations Algorithm

A. Review for the factors, which have identified previous treatment success however may have delayed recovery factors and identified recurrence. (i.e. flare-up due to fall).
B. Patient assessment indicates significant relief of pain and progress towards premorbid function.
   a. Typical measures of treatment response include review of relevant and timely:
      - Patient reported outcome assessment of pain e.g. numerical rating scale.
      - Patient reported disability measures e.g., Back and/or Neck Index.
      - Provider reported physiologic measures e.g., neurological findings.
   b. Most cases return to MTB within 2-4 weeks of care – review patient-specific circumstances for continuation

## Reference


1. Council on Chiropractic Guidelines & Practice Parameters (CCGPP); Algorithms for the Chiropractic Management of Acute and Chronic Spine-Related Pain
2. Local Coverage Determination (LCD)
3. CMS Publication 100-02, *Medicare Benefit Policy Manual*, Chapter 15, Section 240.1.3A
4. Waddell G. The Back Pain Revolution, Churchill Livingstone, 2004
5. Koopmeiners M, et al. Health Care Guideline: Adult Low Back Pain, rev. Nov. 2010; Institute for Clinical Systems Improvement: www.icsi.org
6. Liebenson C. Improving Activity Tolerance in Pain Patients: A Cognitive-Behavioral Approach to Reactivation. Top Clin Chiropr, 2000; 7(4): 6-14
7. Hayden JA, Van Tulder MW, et al. Exercise Therapy for Treatment of Non-Specific Low Back Pain. Cochrane Review, 2005: www.cochrane.org
8. Albight J, et al. Philadelphia Panel Evidence-Based Clinical Practice Guidelines on Selected Rehabilitation
9. Van Hemert M, et al. Overview of Implementation of Outcome Assessment Case Management in Clinical Practice. Washington State Chiropractic Association, 2001: www.wsca@chirohealth.org
10. Liebenson C. Rehabilitation of The Spine, 2nd ed.; Williams & Wilkins, 2007
11. Vernon H. The Neck Disability Index (NDI): Commentary. www.chiro.org/LINKSOUTCOM/Painter_1.shtml
12. Fairbank J, et al. The Oswestry Low Back Pain Disability Questionnaire. Physiotherapy, 1980; 66(18):271-3
13. Yeomans SG. The Clinical Application of Outcomes Assessment. Stamford CT: Appleton & Lange 2000
14. Liebenson C. Rehabilitation of the Spine: A Practitioner's Manual 2nd ed. Baltimore, MD; Lippincott Williams & Wilkins 2007:146-182
15. Adult Low Back Pain 14th ed. Institute For Clinical Systems Improvement. www.icsi.org Revised November 2010
16. Nachemson A, Jonsson E. Neck and Back Pain: The Scientific Evidence of Causes, Diagnosis and Treatment, 2000; Philadelphia: Lippincott Williams & Wilkins
17. Deyo R, Bass J. Lifestyle and Low Back Pain: The Influence of Smoking and Obesity. Spine 1989; 14: 501-6
18. Low Back Pain, Adult Acute and Subacute REVISION DATE: MARCH 2018 / SIXTEENTH EDITION https://www.icsi.org/wp-content/uploads/2019/08/March-2018-LBP-Interactive2.pdf


**Document History:**

| Date | Update |
|---|---|
| 2/6/2018 | Approved by the Clinical Policy Committee |
| 2/22/2018 | Approved by Quality Committee of the Board |
| 2/06/2019 | Approved by Clinical Policy Committee. Annual review. |
| 2/12/2019 | Approved by the UM Subcommittee. Incorporated reference to Medicare LCD language (minor edit, industry standard). |
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