Fulcrum Health, Inc.

Clinical Policies and Guidelines

PHYSICAL MEDICINE

Revised January 2025

Clinical Policies and Guidelines

Preamble

Fulcrum is committed to the philosophy of supporting safe and effective treatment for patients. The medical necessity criteria that follow are guidelines designed to guide both providers and reviewers to the most appropriate treatment based on a patient's unique circumstances. In all cases, reviewers will apply clinical judgment consistent with the standards of good medical practice when applying the guidelines. Determinations are based on guidelines and clinical information provided at the time of the request. Medical necessity decisions may change as new evidence-based information is provided or based on unique aspects of the patient's condition. The treating provider has responsibility for treatment decisions regarding the care of the patient.

Fulcrum develops medical necessity criteria for clinical review requests for therapies and procedures. Developers and contributors to medical necessity criteria include representatives from a multidisciplinary team of local chiropractors (DC), licensed acupuncturists (LAc), massage therapists, physical therapists (PT), and other specialty groups. Fulcrum's guidelines are reviewed yearly and modified when necessary, following a literature search of pertinent and established clinical guidelines and accepted diagnostic imaging practices.

Disclaimer: Fulcrum Health Inc.'s (Fulcrum) policies and guidelines do not constitute medical advice and are not intended to govern or otherwise influence the practice of medicine. These policies are not meant to supplant your normal procedures, evaluation, diagnosis, treatment and/or care plans for your patients. Your professional judgement must be exercised and followed in all respects regarding the treatment and care of your patients. The policies constitute only the reimbursement and coverage guidelines of Fulcrum. Coverage for services varies for individual members in accordance with the terms and conditions of applicable Certificates of Coverage, Summary Plan Descriptions, or contracts with governing regulatory agencies. Fulcrum reserves the right to review and update the guidelines at its sole discretion. Notice of such changes, if necessary, shall be provided in accordance with the terms and conditions of provider agreements and any applicable laws or regulation.

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Licensed Acupuncture Policy

Fulcrum Clinical Guidelines **Licensed Acupuncture Policy**	**Original Date: September 2020 (Fulcrum)**
Physical Medicine – Clinical Decision Making	**Last Revised Date: January 2025**
Guideline Number: ACU100	**Implementation Date: February 2025**

Policy Statement

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:

1. The patient has returned to pre-clinical/pre-onset health status.
2. Meaningful improvement may have occurred; however, documentation does not support that further meaningful gains will be achieved.
3. Meaningful improvement has occurred; however, documentation does not support further supervised 'in-office' treatment.
4. 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, PROMIS10).
5. Meaningful improvement has not been achieved, as measured by activities of daily living (ADL) assessment and/or, standardized outcome assessment tools (OAT) if available, and/or documented in clinical records.
6. There is insufficient information (measurable subjective, objective, or functional changes) documented in the patient health care record to reliably validate the response to treatment.

Purpose

The intent of this policy is to show treatment support and medical necessity guidelines for acupuncture practice. This policy describes the evidence used for determination of maximum therapeutic benefit (MTB).

Scope

Licensed Acupuncturists that are participating network practitioners.

Definitions

Acute Pain: Less than 12 weeks duration

Acupressure: the application of pressure to acupuncture points.

Acupuncture practice means a comprehensive system of health care using Oriental medical theory and its unique methods of diagnosis and treatment. Its treatment techniques include the insertion of acupuncture needles through the skin and the use of other biophysical methods of acupuncture point stimulation, including the use of heat, Oriental massage techniques, electrical stimulation, herbal supplemental therapies, dietary guidelines, breathing techniques, and exercise based on Oriental medical principles.

Acupuncture needle: a needle designed exclusively for acupuncture purposes. It has a solid core, with a tapered point, and is 0.12 mm to 0.45 mm in thickness. It is constructed of stainless steel, gold, silver, or other board-approved materials that can be sterilized according to recommendations of the National Centers for Disease Control and Prevention.

Acupuncture points: specific anatomically described locations as defined by the recognized acupuncture reference texts. These texts are listed in the study guide to the examination for the NCCAOM certification exam.

Chronic Pain: Greater than 12 weeks duration.

- nonspecific, in that it has no identifiable systemic cause (i.e., not associated with metastatic, inflammatory, infectious disease etc.
- not associated with surgery
- not associated with pregnancy

Cupping: a therapy in which a jar-shaped instrument is attached to the skin and negative pressure is created by using suction to move Qi and decrease stagnation

Electrical Stimulation on Needle: Use of an electrical device for stimulating acupuncture points to promote moving of Qi.

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.

Meridians: meridians are invisible energy pathways, or channels, that run through the body. Vital life energy, called *qi* or *chi*, is thought to flow along these meridians, and anything that disrupts and/or stagnates the smooth flow of qi can create dysfunction. There are 12 regular meridians and 20 in total.

Moxibustion (moxa treatment): TCM practice that performed by burning small cones of dried leaves (mugwort) on certain designated points of the body, generally the same points as those used in acupuncture. Adding heat and energy to the body.

NCCAOM: The National Certification Commission for Acupuncture and Oriental Medicine, a not-for-profit corporation organized under section 501(c)(4) of the Internal Revenue Code.

Outcome Assessment Tool (OAT): Standardized self-reported patient questionnaires used to show patient status and progress towards treatment goal. (PROMIS 10, Neck Disability Index, Revised Oswestry Disability Index, Visual Analogue Scale)

Pulse and Tongue: TCM examination to confirm/identify pattern diagnosis.

Recurrent Pain: Pain that is present on less than half the days in a 12-month period occurring in multiple episodes. A recurrence is characterized by pain-related difficulty in performing activities of daily living.

10 Questions: TCM history questions used to make a pattern diagnosis and treatment strategy.

TCM: Traditional Chinese Medicine (Oriental or Eastern approaches to health care conditions)

Treatment Strategy and TCM Diagnoses: Treatment strategy to treat a TCM pattern diagnosis.

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:

1. 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
2. Be an appropriate service, in terms of type, frequency, level, setting, and duration, to the diagnosis or condition; and
3. Help to restore or maintain health.
4. Prevent deterioration of a condition; or

5. 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. If the definitions are different, the benefit contract will prevail.

Procedure

1. Acupuncture visits/units may be considered medically necessary care when ALL the following criteria are met:
   a) pain OR condition is refractory to standard medication therapy, or the member has contraindications or side effects to medications; AND
   b) pain OR condition has resulted in impaired activities of daily living; AND/OR
   c) validated outcomes assessments (OATs) show impairment; AND
   d) there is reasonable expectation that treatment will result in significant improvement over a clearly defined period of time; AND
   e) the provider has documented whether an evaluation has been completed by a primary care physician, neurologist, rheumatologist or pain management specialist.
2. Continuation of acupuncture treatment may be considered medically necessary if the member demonstrates meaningful improvement in condition and symptoms determined by:
   a) For acute or subacute conditions < 12 weeks where initial subjective and objective findings and/or Outcome Assessment Tool (OAT) meet the following criteria:
      i) 3 pt. change in pain assessment score is $\geq$ 5/10 OR
      ii) 2 pt. change in pain assessment score when score is $\leq$4/10 AND
      iii) Overall progress has improved by least 40% (e.g., clinical findings) OR
      iv) OAT with 20% raw score improvement
   b) For chronic conditions > 12 weeks where initial subjective and objective findings and/or OATs meet the following criteria:
      i) 2 pt. change in pain assessment score is > 5/10 OR
      ii) 1 pt. change in pain assessment score when score is <4/10 AND
      iii) Overall progress has improved by least 25% (e.g., clinical findings) OR
      iv) OAT with 10% raw score improvement
3. Providers are required to indicate the applicable ICD10 code when billing for services.
4. The following CPT codes are for informational purposes. Inclusion or exclusion of a procedure, diagnosis or device code(s) does not constitute or imply member coverage or provider reimbursement.
   a) Description of Acupuncture Service - each service counts as one unit. Up to four units equals one visit.
      i) CPT code 97810 – Acupuncture, 1 or more needles; without electrical stimulation, initial 15 minutes of personal one-to-one contact with patient
      ii) CPT code 97811 – Acupuncture without electrical stimulation, each additional 15 minutes of personal one-to-one contact with patient, with re-insertion of needle(s) (List separately in addition to code for primary procedure)
      iii) CPT code 97813 – Acupuncture with electrical stimulation, initial 15 minutes of personal one-to-one contact with the patient
      iv) CPT code 97814 – Acupuncture with electrical stimulation, each additional 15 minutes of personal one-to-one contact with the patient, with re-insertion of needles(s) (List separately in addition to code for primary procedure)

Regulatory, Accreditation and Resources

Medicare NCD & LCD

1. NCD - Acupuncture for Chronic Lower Back Pain (cLBP) (30.3.3) (cms.gov)

State Resources

1. Acupuncture Services (state.mn.us)
2. Sec. 62D.107 MN Statutes
3. Sec. 147B.01 MN Statutes thru Sec. 147B.09 MN Statutes
4. Search - Minnesota Legislature (mn.gov)
5. Sec. 256B.0625 MN Statutes (8f)
6. Minnesota Rules 9505.0195 (Provider Participation)
7. Minnesota Rules 9505.0205 (Provider Records)

Resources

1. Society of Acupuncture Research (SAR)
2. Acupuncture Expert References Group (AERG)
3. Acupuncture Coding and Reimbursement Guidelines (InnoviHealth)

NCQA

1. UM 2 Element A Clinical Criteria for UM Decisions

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Policy History

Date	Summary

8/7/2020	New Document
8/27/2020	Approved by Clinical Policy Committee
9/1/2020	Approved by Utilization Management Subcommittee
3/11/2021	Approved by Clinical Policy Committee
3/18/2021	Approved by Utilization Management Subcommittee
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4/12/2022	Approved by Utilization Management Subcommittee
3/21/2023	Approved by Clinical Policy Committee
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12/07/2023	Approved by Clinical Policy Committee
12/19/2023	Approved by Utilization Management Subcommittee
03/07/2024	Approved by Clinical Policy Committee
03/15/2024	Approved by Utilization Management Subcommittee
01/23/2025	Approved by Clinical Policy Committee
02/04/2025	Approved by Utilization Management Subcommittee

Chiropractic Infant Care Policy

Fulcrum Clinical Guidelines **CHIROPRACTIC INFANT CARE POLICY**	**Original Date: April 2016 (NIA)** **January 2024 (Fulcrum)**
Physical Medicine – Clinical Decision Making	**Last Revised Date: January 2025**
Guideline Number: CLINUM117	**Implementation Date: February 2025**

Policy Statement

While the evaluation, diagnosis, and management of infants falls within the scope of chiropractic practice, participating network providers should not engage in unsafe or unproven services as outlined in this policy. There is insufficient evidence that manual therapy (spinal manipulation, extra-spinal manipulation, and mobilization) results in improved health outcomes, particularly functional outcomes, related to the treatment of both musculoskeletal and non-musculoskeletal infant conditions.

Purpose

This policy will be used to support medically necessary, appropriate, and acceptable treatment of infants defined as ages birth to 24 months.

Scope

Physical medicine participating network practitioners, including rendering chiropractors.

Procedure

1. A therapeutic trial of chiropractic care can be a reasonable approach to management of the infant patient in the absence of conclusive research evidence when clinical experience and patient/parent preferences are aligned.
2. If the infant patient is not showing clinically significant improvement, as evidenced by progress toward documented, specific, measurable, and realistically achievable goals, after a two-week trial of chiropractic care, no additional chiropractic care is indicated, and referral may be appropriate.[1]
3. For infants:
   a) Manual-based therapy (spinal manipulation, extra-spinal manipulation, and mobilization), active care, and passive therapies have not been shown to improve the health outcomes of spine or extremity-based musculoskeletal conditions in infant populations.
   b) The use of manual-based therapy (manipulation and mobilization), active care, and passive therapies have not been shown to improve the health outcomes of non-musculoskeletal conditions in infant populations.[2, 3]
   c) The use of manual-based therapy, active care, and passive therapies have not been proven to be a substitutive treatment for childhood immunizations or the treatment of infectious diseases in infant populations.
4. The following are considered unsafe or unproven services:
   a) The use of spinal and extra-spinal manipulation for non-musculoskeletal conditions is unproven.[3] There is no contemporary chiropractic consensus demonstrating a general agreement among a significant portion of the chiropractic community to support the treatment of non-musculoskeletal conditions, such as the treatment of the common cold, sinus congestion, allergies, sleep disturbances, difficulty nursing, infantile colic, ADHD, asthma, autism, cancer, cerebral palsy, constipation, nocturnal enuresis, and otitis media. The data regarding the use of manual therapy interventions for the treatment of non-musculoskeletal

conditions is sparse, the level of evidence is generally low, and the data are generally inconsistent or conflicting. Wellness care, well-baby checks, and preventive care are not covered. Considerations are derived from peer-reviewed scientific studies published in or accepted for publication by medical or chiropractic journals that meet nationally recognized requirements for scientific manuscripts and that submit most of their published articles for review by experts who are not part of the editorial staff.

b) The use of maintenance or preventative (defined as prevention of any disease or condition or the promotion and enhancement of health after maximum therapeutic benefit has occurred) spinal and extra-spinal manipulation.
c) The use of the following service:
    i) CPT code 97012- Mechanical traction
    ii) CPT code 97014- Unattended electrical stimulation
    iii) CPT code 97032 -Attended electrical stimulation
    iv) HCPCS code G0283 - Electrical stimulation
    v) CPT code 97035 - Ultrasound
    vi) CPT code S9090 or any code used to bill low level laser

5. The following codes will require peer review of clinical documentation to determine medical necessity:
    a) CPT code 97110 – Therapeutic exercise
    b) CPT code 97112 – Neuromuscular reeducation
    c) CPT code 97530 – Activities of daily living
    d) CPT code 98942 – 5-region chiropractic manipulative therapy
    e) CPT code 98943 – Extra-spinal chiropractic manipulative therapy
    f) CPT code 97124 – Massage therapy
    g) CPT code 97140 – Manual therapy
    h) All X-rays
6. Fulcrum has the ultimate authority to determine if treatment is medically necessary and appropriate.

Regulatory, Accreditation and Resources

Medicare NCD & LCD

1. Article - Chiropractic Services – Medical Policy Article (A57889) (cms.gov) (01/01/2020) (IL, MN, WI, NY, CT, ME, MA, NH, RI, VT)
2. LCD - Chiropractic Services (L37387) (cms.gov) (09/29/2021) (AL, GA, TN, SC, VA, WV, NC)
3. LCD - Chiropractic Services (L37254) (cms.gov) (01/26/2023) (KY, OH)

Medicare Billing and Coding: Chiropractic Services

1. Article - Billing and Coding: Chiropractic Services (A58345) (cms.gov) (10/01/2020) (WY, CO, NM, TX, OK, AR, LA, MS, DE, DC, NJ, PA, MD)
2. Article - Billing and Coding: Chiropractic Services (A56273) (cms.gov) (07/07/20223) (IA, KS, MO, NE, IN, MI)
3. Article - Billing and Coding: Chiropractic Services (A56616) (cms.gov). (10/10/2019) (AK, GA, TN, SC, VA, WV, NC)
4. Article - Billing and Coding: Chiropractic Services (A56455) (cms.gov) (11/16/2023) (KY, OH)
5. Article - Billing and Coding: Chiropractic Services (A58412) (cms.gov) (10/01/2020) (FL, VI, PR)
6. Article - Billing and Coding: Chiropractor Services (A57914) (cms.gov) (01/01/2020) (AL, OR, WA, AZ, ND, SD, UT, WY, MT)

NCQA

1. UM 2 Element A Clinical Criteria for UM Decisions

Clinical References

Literature Search

As of August 8, 2022, there is no first-level evidence available in the literature in relation to the effectiveness of manual therapy/manipulation for spinal disorders in the young population. In 2015, the American Academy of Family Physicians published guidelines on infantile colic, noting that "]physical therapies for colic include chiropractic and osteopathic manipulation, massage, and acupuncture. A Cochrane review[4] found insufficient evidence to support chiropractic or osteopathic manipulation, because many studies were small, nonblinded, and had a high likelihood of bias. Trials of acupuncture and infant massage have had conflicting results, and further studies are needed to determine their benefits and harms."[5] A single-blind, randomized controlled trial (RCT) comparing the effect of chiropractic care to treat colic reported no statistically significant difference between the control group of colicky infants and the experimental group receiving care,[6] and a second RCT reports that "musculoskeletal indicators were not shown to be predictive of an increased benefit for colicky infants from chiropractic treatment."[7]

Additionally, the American Academy of Pediatrics, in the 2017 *Pediatric Integrative Medicine* guidelines state, "High-quality evidence supporting effectiveness of spinal manipulation for nonmusculoskeletal concerns is lacking, especially in infants and children, for whom the risks of adverse events may be the highest because of immature stability of the spine… Serious complications are possible with chiropractic treatment of children, but such adverse effects are rare and related to high-velocity, extension, and rotational spinal manipulation."[3] No guidelines, systematic reviews, or randomized controlled trials were discovered in a literature search regarding the treatment of infant musculoskeletal conditions with spinal or extra-spinal manipulation, mobilization, massage therapy, mechanical traction, electrical stimulation, ultrasound therapy, or low-level laser therapy (LLLT).

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Policy History

Date	Summary
November 2023	NIA/Fulcrum Policy Reconciliation
12/07/2023	Approved by Clinical Policy Committee
12/19/2023	Approved by Utilization Management Subcommittee
03/07/2024	Approved by Clinical Policy Committee
03/15/2024	Approved by Utilization Management Subcommittee
01/23/2025	Approved by Clinical Policy Committee
02/04/2025	Approved by Utilization Management Subcommittee

Chiropractic Manipulative Treatment

Fulcrum Clinical Guidelines **Chiropractic Manipulative Treatment**	**Original Date: June 2018 (Fulcrum)**
Physical Medicine – Clinical Decision Making	**Last Revised Date: January 2025**
Guideline Number: CLINUM 101	**Implementation Date: February 2025**

Policy Statement

Fulcrum Health, Inc. (Fulcrum) has developed this policy to offer objective standardized criteria to support the accuracy of Chiropractic Manipulative Treatment (CMT) selection and utilization.

Purpose

To apply standardized coding criteria to support selection of Chiropractic Manipulation Treatment.

Scope

Physical medicine participating network practitioners, including rendering chiropractors.

Definitions

Chiropractic Manipulation Treatment (CMT) is a form of manual treatment to influence joint and neurophysiological function. This treatment may be accomplished using a variety of techniques.

Procedure

1. For spinal manipulation, the assigned CMT must be patient-centered and selected based upon the subjective complaint presentation and objective exam findings.
   a) The diagnosis must support a neuromusculoskeletal condition.
   b) Technique-based protocols, office routine, or provider philosophy are not acceptable methods for determining CMT code selection.
   c) Wedges or Blocking used to create a 'traction' effect using body weight is considered part of the CMT procedure.
   d) The treatment is performed in the region or adjacent region to the complaint.
   e) There are no contraindications to manipulation.
2. For extra-spinal, Fulcrum considers an initial trial (up to 4-6 weeks provided the documentation shows specific and measurable evidence of trending progress**…"**) of extraspinal manipulation/mobilization clinically appropriate for patients presenting with neuromusculoskeletal disorders involving the shoulder, elbow (see exclusions below), wrist/hand (see exclusions below), hip, knee, ankle and foot (see exclusions below), when the following criteria are satisfied:
   a) A neuromusculoskeletal diagnosis for an extremity complaint has been documented;
   b) There are no contraindications to manipulation or mobilization;
   c) The patient expresses a defined preference for manipulation or mobilization;
   d) Plausible alternative treatment options have not been shown to be more effective; and
   e) The patient's healthcare record documents manipulation or mobilization of an extremity joint or joints directly related to the diagnosis.

The daily treatment record must document the specific segments included in the CMT in the treatment section. Documentation should include the type of CMT applied.

CPT	CPT Description	Medical record documentation must include:
98940	Chiropractic manipulative treatment (CMT) involving one to two spinal regions	1. A complaint involving at least one spinal region; AND 2. An examination of the corresponding spinal region(s); AND 3. A diagnosis and manipulative treatment of a condition involving at least one spinal region. 4. The specific spinal segments treated need to be listed in the treatment plan on that date of service. 5. Claim must record a diagnosis code in the applicable region(s).
98941	Chiropractic manipulative treatment (CMT) involving three to four spinal regions	1. A complaint involving at least three spinal regions; AND 2. An examination of the corresponding spinal regions; AND 3. A diagnosis and manipulative treatment of conditions involving at *least three* spinal regions. 4. The specific spinal segments treated need to be listed in the treatment plan on that date of service. 5. Claim must record a diagnosis code in all the applicable regions.
98942	Chiropractic manipulative treatment (CMT) involving five spinal regions	1. A complaint involving five spinal regions; AND 2. An examination of the corresponding spinal regions; AND 3. A diagnosis and manipulative treatment of conditions involving five spinal regions. 4. The specific spinal segments treated need to be listed in the treatment plan on that date of service. 5. Claim must record a diagnosis code in all the applicable regions.
98943	Extraspinal, 1 or more regions	1. A complaint involving one of the regions listed below** AND 2. An examination of the corresponding regions; AND 3. A diagnosis and manipulative treatment of conditions involving the affected region(s). 4. The specific spinal segments treated need to be listed in the treatment plan on that date of service. 5. Claim must record a diagnosis code relative to the applicable region. **Extraspinal regions are head (excludes atlanto-occipital and includes temporomandibular joint*), lower and upper extremities, rib cage (excludes costotransverse and costovertebral joints), and abdomen. *May be excluded as a non-covered service

Regulatory, Accreditation and Resources

Medicare NCD & LCD

1. Article - Chiropractic Services – Medical Policy Article (A57889) (cms.gov) (01/01/2020) (IL, MN, WI, NY, CT, ME, MA, NH, RI, VT)
2. LCD - Chiropractic Services (L37387) (cms.gov) (09/29/2021) (AL, GA, TN, SC, VA, WV, NC)
3. LCD - Chiropractic Services (L37254) (cms.gov) (01/26/2023) (KY, OH)

Medicare Billing and Coding: Chiropractic Services

1. Article - Billing and Coding: Chiropractic Services (A58345) (cms.gov) (10/01/2020) (WY, CO, NM, TX, OK, AR, LA, MS, DE, DC, NJ, PA, MD)
2. Article - Billing and Coding: Chiropractic Services (A56273) (cms.gov) (07/07/20223) (IA, KS, MO, NE, IN, MI)
3. Article - Billing and Coding: Chiropractic Services (A56616) (cms.gov). (10/10/2019) (AK, GA, TN, SC, VA, WV, NC)
4. Article - Billing and Coding: Chiropractic Services (A56455) (cms.gov) (11/16/2023) (KY, OH)
5. Article - Billing and Coding: Chiropractic Services (A58412) (cms.gov) (10/01/2020) (FL, VI, PR)
6. Article - Billing and Coding: Chiropractor Services (A57914) (cms.gov) (01/01/2020) (AL, OR, WA, AZ, ND, SD, UT, WY, MT)

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Policy History

Date	Summary
02/06/2018	Approved by Clinical Policy Committee
02/06/2019	Approved by UM Subcommittee
03/12/2020	Approved by Clinical Policy Committee
03/21/2020	Approved by UM Subcommittee
3/11/2021	Approved by Clinical Policy Committee
3/18/2021	Approved by UM Subcommittee
3/17/2022	Approved by Clinical Policy Committee
3/29/2022	Approved by UM Subcommittee
3/21/2023	Approved by Clinical Policy Committee
05/02/2023	Approved by UM Subcommittee
November 2023	NIH policy (NIA_CG_604) and Fulcrum policy reconciliation.
12/07/2023	Approved by Clinical Policy Committee
12/19/2023	Approved by UM Subcommittee
03/07/2024	Approved by Clinical Policy Committee
03/15/2024	Approved by Utilization Management Subcommittee
01/23/2025	Approved by Clinical Policy Committee
02/04/2025	Approved by Utilization Management Subcommittee

Chiropractic Therapeutic Treatment Policy

Fulcrum Clinical Guidelines **Chiropractic Therapeutic Treatment Policy**	**Original Date: June 2018 (Fulcrum)**
Physical Medicine – Clinical Decision Making	**Last Revised Date: January 2025**
Guideline Number: CLINUM100	**Implementation Date: February 2025**

Policy Statement

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.

Purpose

This policy was written to provide a consistent determination of medical necessity in the review and management of neuromusculoskeletal disorders.

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:

1. The patient has returned to pre-clinical/pre-onset health status.
2. Meaningful improvement may have occurred; however, documentation does not support that further meaningful gains will be achieved.
3. Meaningful improvement has occurred; however, documentation does not support further supervised 'in-office' treatment.
4. 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).
5. Meaningful improvement has not been achieved, as measured by activities of daily living (ADL) assessment and/or, standardized outcome assessment tools (OAT) if available, and/or documented in clinical records.
6. 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 for the appropriate level of care is dependent upon the presenting symptomatology and medical history. Each level of care category is distinct and provides specific parameters for the duration of treatment based on presenting clinical evidence. Level of Care categories are:

1. Acute = symptom onset within 6 weeks of office presentation
2. Subacute = symptom onset within 6 to 12 weeks of office presentation
3. Chronic = symptoms present for 12 weeks or greater prior to office presentation

Uncomplicated patient presentations are nontraumatic, have no neurologic deficits and no indications of potentially serious pathologies.

Complications include individual attributes that may delay recovery and must be considered in the total

management of neuromusculoskeletal conditions. Individual attributes include but are not limited to traumatic onset, neurologic deficits, 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:

1. 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
2. Be an appropriate service, in terms of type, frequency, level, setting, and duration, to the diagnosis or condition; and
3. Help to restore or maintain health;
4. Prevent deterioration of a condition; or
5. 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.

Qualified Health Professional (QHP): 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).

Procedure

1. 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".
2. 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.
        i) Subjective:
            1) 2 pt. change in subjective pain when pain is >5/10
            2) 1 pt. change in subjective pain when pain is <4/10
        ii) Objective or ADL:
            1) Overall relative progress is at least 25% (e.g., ROM or specific ADL disturbance).
        iii) Functional Outcome Assessment:
            1) OAT= 10% score improvement
3. NCDs, LCA and State specific regulations will be utilized for the clinical review process for Medicaid and Medicare recipients.
4. The QHP will assess patient and provider reported clinical information. This reported information may be found in:
    a) Daily clinical records
    b) Fulcrum developed authorization forms and/or assessment.
    c) Standard outcome assessment tools (OATs) (i.e. Revised Oswestry, Neck Disability Index)
    d) Prior clinical reviewer notes
5. The following tables are used to facilitate and guide review of treatment plans and service recommendations by the QHP.
    a) Table 1a. Initial Course of Care

b) Table 1b. Ongoing treatment recommendations/support
c) Table 1c. Flare-ups/Exacerbations
d) Table 2. Decision elements for ongoing treatment recommendations/support

Table 1a. Initial Course of Care				
Case Type:	**Uncomplicated**	**Complicated**	**Moderate**	**Severe**
Acute (4-8 weeks for initial care)	Not to exceed 8 visits	Not to exceed 12 visits	Not to exceed 16 visits	Not to exceed 20 visits

Table 1b. Ongoing Treatment Recommendations/Support					
	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 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 1c. Flare-ups/Exacerbations			
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 for ongoing treatment recommendations/support. Need 4 of 7					
Decision Element	1	2	3	4	5
	Uncomplicated Progress Stalled	**Uncomplicated - near MTB**	**Complicated - Moderate**	**Complicated - Severe**	**Complicated not improving**
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 Reflexes normal	No radiculopathy Reflexes normal	Radiculopathy (Improvement noted) Reflexes (improved)	Radiculopathy (Improvement noted) Reflexes (improved)	Radiculopathy (no improvement) Reflex (no improvement)
iii. Provider and/or Patient reported Complaint-Specific Data	Continued issues with pain without lasting meaningful change (previous 60 days) Frequent exacerbations despite	Low pain levels (less than 4/10). Low pain frequency Significant pain relief	Moderate pain (3-7 /10) 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

	care. No attempted withdrawal from care				
iv. Individual ADL's difficulties reported in Fulcrum's Assessment and/or 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. Disability per activity (2-4)	No ADL improvement or worsening scores for the same episode
v. Disability level (if applicable) - Total OATs Scores	Exacerbations that show little to no lasting stability OAT score less than 20% on an ongoing basis	Minimal Disability Scores OAT score less than 20%	Minimal to Moderate Disability Scores (20 - 40% disability) *	Moderate to Severe Disability but improving Scores (40-80 %disability) * 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 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.

6. 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
      i) Initial clinical trial, up to sixty days.
      ii) Within the initial clinical trial there must be resolution of the condition or greater than 25% improvement. Measured by:
         (1) 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.
            (i) Patient reported assessment of pain e.g. numerical scale.
            (ii) Patient reported disability measures e.g., Back and/or Neck Index; Oswestry
         (2) Continuation of care is supported (see Sub-Acute Algorithm)
         (3) If continuation of care is not supported, see table 1.b. for transition message.
   b) Sub-Acute Musculoskeletal Algorithm
      i) 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). Measured by:
         (1) 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.
            (a) Patient reported assessment of pain e.g. numerical scale.
            (b) Patient reported disability measures e.g., Back and/or Neck Index; Oswestry –
         (2) Continuation of care is supported refer to table 1.b for recommendation.

(3) 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/Exacerbation Algorithm
   i) 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).
   ii) Patient assessment indicates significant relief of pain and progress towards premorbid function.
      (1) Typical measures of treatment response include review of relevant and timely:
         (a) Patient reported outcome assessment of pain e.g. numerical rating scale.
         (b) Patient reported disability measures e.g., Back and/or Neck Index.
         (c) Provider reported physiologic measures e.g., neurological findings.
      (2) Most cases return to MTB within 2-4 weeks of care – review patient-specific circumstances for continuation.

Regulatory, Accreditation and Resources

Medicare NCD & LCD

1. Article - Chiropractic Services – Medical Policy Article (A57889) (cms.gov) (01/01/2020) (IL, MN, WI, NY, CT, ME, MA, NH, RI, VT)
2. LCD - Chiropractic Services (L37387) (cms.gov) (09/29/2021) (AL, GA, TN, SC, VA, WV, NC)
3. LCD - Chiropractic Services (L37254) (cms.gov) (01/26/2023) (KY, OH)

Medicare Billing and Coding: Chiropractic Services

1. Article - Billing and Coding: Chiropractic Services (A58345) (cms.gov) (10/01/2020) (WY, CO, NM, TX, OK, AR, LA, MS, DE, DC, NJ, PA, MD)
2. Article - Billing and Coding: Chiropractic Services (A56273) (cms.gov) (07/07/20223) (IA, KS, MO, NE, IN, MI)
3. Article - Billing and Coding: Chiropractic Services (A56616) (cms.gov). (10/10/2019) (AK, GA, TN, SC, VA, WV, NC)
4. Article - Billing and Coding: Chiropractic Services (A56455) (cms.gov) (11/16/2023) (KY, OH)
5. Article - Billing and Coding: Chiropractic Services (A58412) (cms.gov) (10/01/2020) (FL, VI, PR)
6. Article - Billing and Coding: Chiropractor Services (A57914) (cms.gov) (01/01/2020) (AL, OR, WA, AZ, ND, SD, UT, WY, MT)

NCQA

a) UM 2 Element A Clinical Criteria for UM Decisions

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Policy History

Date	Summary
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.
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Definition of a Pediatric Patient

Fulcrum Clinical Guidelines **Definition of a Pediatric Patient**	**Original Date: June 2018**
Physical Medicine – Clinical Decision Making	**Last Revised Date: January 2025**
Guideline Number: CLINUM 112	**Implementation Date: February 2025**

Policy Statement

A pediatric patient is defined as one who has yet to reach their 18th birthday.

Policy History

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03/18/2021	Approved by UM Subcommittee
03/17/2022	Approved by Clinical Policy Committee
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Definition and Application of Complicating Factors in the Utilization Management Process

Fulcrum Clinical Guidelines **Definition and Application of Complicating Factors in the Utilization Management Process**	**Original Date: June 2018**
Physical Medicine – Clinical Decision Making	**Last Revised Date: January 2025**
Guideline Number: CLINUM 116	**Implementation Date: February 2025**

Policy Statement

Complicating factors are those influences, which have been identified as having a significant negative influence on the natural history of a condition. These factors can be categorized as influencing the severity and/or duration and/or recurrence rate of a condition. Utilization management decision-making considers the presence/absence of complicating factors and their impact on functional outcome scores when determining the necessity/appropriateness of treatment interventions.

Purpose

To define the term complicating factors and how they impact Utilization Management decisions.

Procedure

Overall screening and counseling are recommended for tobacco use, obesity, poor diet, and physical inactivity which are key risk factors for chronic disease and are of paramount importance to the health of the public [1].

The following information summarizes patient characteristics, which have been evaluated for their potential as complicating factors. These factors can be broadly categorized as individual influences, psychological deterrents, occupational effects, and anatomic or physiologic findings.

1. Individual Influences
    a) **Heredity:** "Genetic factors influence certain spinal disorders, such as spondylolisthesis, scoliosis and ankylosing spondylitis. A few clinical studies suggest that there may sometimes be a familial or genetic predisposition to disc prolapse. However, this is of little relevance to nonspecific back pain." There is no evidence that genetic or constitutional factors determine who is going to become back disabled.
    b) **Gender:** "Men and women get more or less the same back pain."
    c) **Age:** "The prevalence of back pain increases from our teens to our late 40s or early 50s but may fall slightly above the age of 60 years. In those who do continue to have back pain, it is likely to be more frequent or more constant with increasing age."
    d) **Body Build:** There is no strong relationship between height, weight, body build and back pain. "Doctors and therapists frequently comment on unequal leg length, but most studies fail to prove any significant relation to back pain."
    e) **Physical Fitness:** "There is clinical evidence that people with chronic back pain are less fit, but this could be an effect rather than the cause." "There are strong theoretic reasons and some clinical evidence to suggest that physically fit patients may make a more rapid recovery from acute back pain and be less likely to develop chronic pain and disability."
    f) **Smoking:** Occupation, social strata, and education all affect the prevalence of smoking. These factors may have more of an influence upon the occurrence and duration of back pain than smoking. A higher risk of back pain was found in people who smoked three or more packs per day. Overall, the effect of smoking on back pain is weak.

g) **Social Class:** "Social class reflects occupation, particularly manual vs. nonmanual, and social disadvantage. The prevalence of back pain may be slightly greater in those from a lower social class. There is a clear and marked increase in work loss due to back pain with lower social class."
h) **Symptom Duration:** There is no current evidence to support the premise that patients who delay professional care for more than a week after the onset of complaints are more likely to experience a delayed recovery.
i) **Prior History:** A personal history of prior episodes of back pain is the most significant predictor of future occurrences.

2. Psychosocial Deterrents

There is strong evidence that psychosocial variables are strongly linked to the transition from acute to chronic pain disability. There is strong evidence that psychological distress i.e., anxiety, depressive symptoms, increased bodily awareness, anger, fears and uncertainty can be associated with the onset of back and neck pain, and related disability. The evidence is strong that psychosocial variables generally have more impact than biomedical or biomechanical factors on back pain disability.

"There is strong evidence that attitudes, cognitions, and fear-avoidance beliefs are strongly related to the development of pain and disability." There is strong evidence that passive coping and pain cognitions such as catastrophizing are strongly related to pain and disability.

3. Occupational Factors
   a) **Heavy manual work:** There is conflicting evidence that people performing heavy manual labor report slightly more back pain. They do report more lower back work injuries. The impact of back pain on individuals in heavy manual jobs is significant. They are more likely to be off work and remain off work longer. This may, however, be primarily due to the effect of their back pain rather than the cause. It may also reflect medical advice.
   b) **Lifting**: Back injuries are more commonly reported in jobs that involve:
      i) Heavy lifting
      ii) Lifting objects which are bulky or must be held away from the body
      iii) Lifting from the floor
      iv) Frequent lifting

      It is difficult to measure the impact of lifting due to the influences such as psychosocial e.g. job dissatisfaction, frequency and rate of lifting and an individual's strength.
   c) **Twisting**: "Several studies and strong biomechanical evidence suggest that the risk of back injury is greater when lifting is combined with bending and particularly twisting."
   d) **Sitting**: Prolonged sitting in one position aggravates existent back pain. There is no convincing evidence that prolonged sitting increases the prevalence of back pain.
   e) **Static Load:** There is an increased risk of neck pain for persons heavily exposed to work tasks that maintain a static load such as assembly line jobs and visual display unit work.
4. Anatomic/Physiologic Findings
   a) **Symptomatic herniated disc:** Defined as when symptom distribution, neuromotor exam and provocative testing clinically correlate with pathoanatomic findings evidenced on advanced imaging.
   b) **Adult Scoliosis:** The incidence of back pain is similar to the general population. There is reason to believe that the persistence of back pain is greater with the adult scoliotic group. Back pain is more common in patients with lumbar curves and in patients with thoracolumbar and lumbar curves > 45 degrees with apical rotation and coronal imbalance.
   c) **Slight disc degeneration, Spondylosis, Spondylolisthesis, Spina Bifida and Transitional vertebrae:** Almost half of all patients with any of these findings do not have back pain, so the finding may be unrelated.

Regulatory, Accreditation and Resources

NCQA

1. UM 2 Element A Clinical Criteria for UM Decisions

Clinical References

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Policy History

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Evaluation and Management

Fulcrum Clinical Guidelines **Evaluation and Management**	**Original Date: June 2018 (NIA)** **June 2018 (Fulcrum)**
Physical Medicine – Clinical Decision Making	**Last Revised Date: January 2025**
Guideline Number: CLINUM 107	**Implementation Date: February 2025**

Policy Statement

The level of Evaluation and Management (E/M) services must be determined by either Medical Decision Making (MDM) elements or time. The E/M services may be considered appropriate and/or medically necessary when the history and examination findings are documented based on the clinical judgment of the provider and benefit coverage criteria are met.

Purpose

This policy has been developed to describe the criteria that Fulcrum Health, Inc. (Fulcrum) uses to conduct utilization review (UR) determinations concerning the appropriateness and/or medical necessity for (E/M) coding.

Definitions

Assessment: Assessment refers to the professional skills used to gather data by observation, patient inquiry, and may include limited objective testing and measurement to make clinical judgments regarding the patient's condition(s). Assessments performed on each visit help to determine changes in the patient's status since the last visit/treatment day and whether the planned procedure or service should be modified. Based on these assessment data, the clinician may make judgments about progress toward goals and/or determine that a more complete evaluation or re-evaluation.

Episode of care: The consultation and skilled care provided by a clinician. An episode may include the evaluation and treatment related to multiple conditions.

A. For a new health problem or condition, which begins with the initial evaluation and ends with the reporting of discharge status; or
B. For a previously treated health problem or condition, which is preceded by at least 3 months without treatment; or
C. For a previously treated health problem or condition, which is preceded by a separation from care due to a surgical procedure directly related to the health problem or condition; or
D. For a chronic/recurrent health problem or condition, which consists of a series of treatment intervals marked by one or more brief separations from care.

New patient: A new patient is one who has not been seen by the health care provider or any similar specialty in that clinic during the prior three (3) years.

Established patient: An established patient is one who has received professional services from the provider or from another physician of the same specialty who belongs to the same group practice, during the past three years.

Patient important outcomes: Reports or measures representing what is most important to patients about a condition and its treatment. Patient important outcomes often relate to symptoms, signs, functional status, perceptions, or other aspects such as convenience and tolerability.

Re-evaluation: The re-evaluation provides additional objective information not included in other documentation (e.g., assessments of progress between visits). Re-evaluation is separately reportable and is periodically indicated during an episode of care when the professional assessment of a clinician indicates a significant improvement, or decline, or change in the patient's condition or functional status that was not anticipated in the plan of care.

Procedure

1. The level of E/M code may be supported by either **Medical Decision Making (MDM) elements** or **Time** (timed activity directly related to the E/M criteria). See table insert for more detailed descriptions of MDM and Time requirements.
   a) Medical Decision Making (MDM): Two of the three elements must be documented to support the level of E/M service reported. Medical Decision making includes establishing diagnoses, assessing the status of a condition, and/or selecting a management option, and can be defined by three elements:
      i) Problem Element: number and complexity of problems addressed.
      ii) Data Element: amount and or complexity of data to be reviewed and analyzed.
      iii) Risk Element: risk of complications and/or morbidity or mortality.
   b) Time with activity directly related to the E/M criteria Includes face-to-fact and non-face-to-face services. It is highly recommended to document both start and stop times when selecting this method for determining level of E/M code.

2. Established E/M coverage criteria are:
   a) An established patient exam may be considered medically necessary and supported if performed 30+ days since last evaluation OR within 30 days if one of the following indications is documented:
      i) The patient presents with new clinical findings;
      ii) There is a significant change in the patient's condition; or
      iii) The patient has failed to respond to the therapeutic interventions outlined in the current plan of care.
   b) The documentation of the established patient E/M must include all of the following elements:
      i) An evaluation of progress toward current goals;
      ii) Making a professional judgment about continued care; and
      iii) Making a professional judgment about revising goals and/or treatment or terminating services.

3. Review the following table to determine appropriate E/M code selection criteria.

E/M Code level	**MDM Medical Decision Making**	**Problem Element** Number and Complexity of Problems Addressed	**Data Element** Amount and/or Complexity of Data to be Reviewed and Analyzed.	**Risk Element** Risk of Complications and/or Morbidity or Mortality	**Time** Time with activity directly related to the E/M criteria
99202 New 99212 Est	Straight-forward	1 self-limited/minor problem	**Minimal or none**	Minimal risk of morbidity from additional diagnostic testing or treatment	99202 = 15-29 minutes 99212 = 10-19 minutes
99203 New 99213 Est	Low	2 or more self-limited / minor problem 1 stable chronic problem 1 acute uncomplicated injury	**Limited** *(Must meet the requirements of at least 1 of the 2 categories)* **Category 1:** Any combination of 2 from the following: Review of prior external	Low risk of morbidity from additional diagnostic testing or treatment	99203 = 30-44 minutes 99213 = 20-29 minutes

E/M Code level	MDM Medical Decision Making	Problem Element Number and Complexity of Problems Addressed	Data Element Amount and/or Complexity of Data to be Reviewed and Analyzed.	Risk Element Risk of Complications and/or Morbidity or Mortality	Time Time with activity directly related to the E/M criteria
			note(s) from each unique source*; review of the result(s) of each unique test*; ordering of each unique test* **or** **Category 2: Assessment requiring an independent historian(s)** *(For the categories of independent interpretation of tests and discussion of management or test interpretation, see moderate or high)*		
99204 New 99214 Est	Moderate	1 or more chronic illness with exacerbation, progression, or side effects of treatment 2 or more chronic illnesses 1 undiagnosed new problem with uncertain prognosis 1 acute illness with systemic symptoms 1 acute complicated injury	**Moderate** *(Must meet the requirements of at least 1 out of 3 categories)* **Category 1:** Any combination of 3 from the following: Review of prior external note(s) from each unique source*; Review of the result(s) of each unique test*; Ordering of each unique test*; Assessment requiring an independent historian(s) **or** **Category 2:** Independent interpretation of a test performed by another physician/other qualified health care professional (not separately reported); **or** **Category 3:** Discussion of management or test interpretation with external physician/other qualified health care professional\appropriate source (not separately reported)	**Moderate risk of morbidity from additional diagnostic testing or treatment** *Examples only:* Prescription drug management Decisions regarding: minor surgery with identified patient or procedure risk factors elective major surgery without identified patient or procedure risk factors Diagnosis or treatment significantly limited by social determinants of health	99204 = 45-59 minutes 99214 = 30-39 minutes
99205 New 99215 Est	High	1 or more chronic illness with severe exacerbation, progression, or side effects of treatment 1 acute or chronic	**Extensive** *(Must meet the requirements of at least 2 out of 3 categories)* **Category 1:** Any combination of 3 from the following: Review of prior external note(s)	**High risk of morbidity from additional diagnostic testing or treatment** *Examples only:* Drug therapy requiring	99205 = 60-74 minutes 99215 = 40-54 minutes

E/M Code level	MDM Medical Decision Making	Problem Element Number and Complexity of Problems Addressed	Data Element Amount and/or Complexity of Data to be Reviewed and Analyzed.	Risk Element Risk of Complications and/or Morbidity or Mortality	Time Time with activity directly related to the E/M criteria
		illness or injury that poses a threat to life or bodily function	from each unique source*; Review of the result(s) of each unique test*; Ordering of each unique test*; Assessment requiring an independent historian(s) **or** **Category 2:** Independent interpretation of a test performed by another physician/other qualified health care professional. (not separately reported); **or** **Category 3:** Discussion of management or test interpretation with external physician/other qualified health care professional/appropriate source (not separately reported)	intensive monitoring for toxicity Decision regarding: elective major surgery with identified patient or procedure risk factors emergency major surgery hospitalization not to resuscitate or to de-escalate care because of poor prognosis	

*Each unique test, order, or document contributes to the combination of 2 or combination of 3 in Category 1.

Regulatory, Accreditation and Resources

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Clinical References

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Policy History

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02/18/2018	New Document
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Record Keeping and Documentation Standards: Chiropractic

Fulcrum Clinical Guidelines **Record Keeping and Documentation Standards-Chiropractic**	**Original Date: June 2018 (NIA)** **May 2010 (Fulcrum)**
Physical Medicine – Clinical Decision Making	**Last Revised Date: January 2025**
Guideline Number: CLINUM120	**Implementation Date: February 2025**

Policy Statement

Fulcrum Health, Inc. network providers must maintain clinical record keeping practices for paper-based records and/or electronic health records (EHR). These records must comply with Fulcrum Health standards regarding confidentiality, availability, organization, and quality medical record documentation.

Purpose

Consistent and complete documentation is an essential component of quality patient care. Network providers must maintain documents as outlined below. Failure to maintain adequate medical records could result in claim denial or recoupment, increased case audits and/or change in network participation status.

Procedure

1. General Guidelines
   a) Documentation should clearly reflect why the skills of a network provider are needed. The service is considered a *skilled service* if the inherent complexity of the service is such that it can be performed safely and/or effectively only by or under the supervision of a network provider. The deciding factors are always whether the services are considered reasonable, effective treatments requiring the skills of a provider.
   b) All records (both digital and handwritten) must be legible, which is defined as the ability of at least two people to read and understand the documents.
   c) Each date of service must adequately identify the patient and include the treating provider's signature and credentials. Each subsequent page in the record must also contain the patient's name or ID number.
   d) All chart entries must be dated with the month, day, and year.
   e) Records must also be in chronological order and if handwritten they must be in permanent ink with original signatures. Electronic entries should be made with appropriate security and confidentiality provisions.
   f) Patient demographics including name, address, home and work telephone numbers, gender, date of birth, occupation, and marital status must be provided.
   g) Any working diagnosis(es) or condition description similar to the appropriate ICD code must be provided. If one is not applicable/allowed, it must be documented and consistent with the associated findings.
   h) The reason for the encounter or referral (i.e., presenting complaint(s)).
   i) Each date of service must include the subjective complaint(s), objective findings, assessment, diagnosis, treatment/ancillary diagnostic studies performed with results, and any recommendations, instructions, or patient education.
   j) Services must be documented in accordance with Current Procedural Terminology (CPT®) coding criteria (e.g., location (body region), time component).
   k) Adverse events associated with treatment should be recorded in the patient chart.
   l) Copies of relevant reports and correspondence with other skilled practitioners; including, but not limited to diagnostic studies, laboratory findings, and consultations.

m) Copies of reports and correspondence related to treating provider's diagnostic studies, laboratory findings, and consultations, including rationale for the service or consult and findings, conclusions, and recommendations.
n) A copy of the discharge summary must be provided if the patient has a current authorization with a different provider and is seeking services with a new provider. Treatment should not duplicate services provided in multiple settings.
o) Appropriate consent forms should be included when applicable.
p) A key or summary of terms when non-standard abbreviations are used. Another practitioner should be able to read the record and have a clear understanding of the patient's condition and treatment rendered.
q) Any corrections to the patient's record must be made legibly in permanent ink (single line through the error), dated, and authenticated by the person making the correction(s). Electronic documentation should include the appropriate mechanism indicating that a change was made without the deletion of the original record.

2. The evaluation must include:
   a) Documentation to support the medical need for a course of treatment through objective findings and subjective patient reporting.
   b) A list of the conditions and complexities and description of the impact of the conditions and complexities on the prognosis and/or the plan for treatment such that it is clear to the peer reviewer or other healthcare professionals that the planned services are reasonable and appropriate for the patient.
   c) The patient's general demographics, prior medical, familial, and social history, including, but not limited to accidents, surgeries, medications, illness, living environment, general health status (self, family or caregiver report), medications, co-morbidities and history or identification of any past or current treatment for the same condition.
   d) All diagnoses related to the patient's condition and contraindications to treatment as well as safety risks must be provided. This may also include impairment, activity limitations, and participation restrictions.
   e) Baseline evaluation, including current and prior functional status (functional mobility and ADL deficits).
   f) Systems review consistent with the nature of the complaint(s) and relevant historical information should be included in documentation.
   g) Objective measures and/or standardized orthopedic and neurological testing demonstrating a decline in functional status must be provided. (Note: Treatment must not be focused on returning to activities beyond normal daily living). Assessment tools used during the evaluation should be valid, reliable, relevant, and supported by appropriate clinical best practices guidelines.
   h) Outcome assessment measures are preferred. Scores alone may not be used as the sole criteria for determining a patient's medical need for skilled intervention. Test information must be linked to difficulty with or inability to perform everyday tasks.
   i) In the absence of objective measures, the evaluation must include detailed clinical observations of current skill sets, patient interview/questionnaire, and/or informal assessment supporting functional mobility/ADL deficits and the medical need for skilled services. The documentation must clearly state the reason formal testing could not be completed.
   j) Functional outcome assessments and/or standardized test results with raw scores, standardized scores, and score interpretations.
   k) Detailed clinical observations, as well as prognosis and rehab potential.

l) Contraindications to care, with an explanation of their current management.

3. Treatment plan of care must be individualized, goal-oriented, and aimed at restoring specific functional deficits. Plan of care elements are:
   a) The patient's age, date of birth, and date of evaluation
   b) Medical history and background
   c) All diagnoses related to the patient's condition and contraindications to treatment as well as safety risks.
   d) Date of onset or current exacerbation of the patient's condition
   e) Description of baseline functional status/limitations based on standardized testing administered or other assessment tools.
   f) Meaningful clinical observations; the patient's response to the evaluation process; and interpretation of the evaluation results, including prognosis for improvement and recommendations for the amount, frequency, and duration of services.
   g) The plan of care must include goals detailing type, amount, duration, and frequency of services required to achieve targeted outcomes. The frequency and duration must also be commensurate with the patient's level of disability as well as accepted standards of practice while reflecting clinical reasoning and current evidence.
   h) Visits requested must not exceed the frequency and duration supported in the plan of care.
   i) Treatment diagnosis and specific contraindications to treatment
   j) Baseline/current functional status/limitations as compared to pre-episode functional status.
   k) Patient-specific functional goals that are measurable, attainable, time-specific, and sustainable. The initial plan of care should not exceed 4 weeks.
   l) Proposed frequency and duration of treatment within a reasonable and generally predictable time period
   m) Specific therapeutic interventions to be provided.
   n) Predicted level of improvement in function (prognosis)
   o) Specific discharge plan
4. Updated plan of care elements are:
   a) Time frame for current treatment period
   b) Total visits from start of care.
   c) Change in objective outcome measures and standardized testing compared to baseline and/or most recent reassessment/updated plan of care.
   d) Measurable overall progress toward each goal including whether goal has been met or not met. Goals should be updated and modified as appropriate.
   e) Modification of treatment interventions in order to meet goals.
   f) Home program and self-management teaching
   g) Collaboration with other services/professionals
   h) Measurable short- and long-term functional goals that are achievable within the length of time services are requested.
   i) Individualized targeted outcomes that are linked to functional limitations outlined in the most recent evaluation.
   j) Intervention selections must be evidence-based and chosen to address the targeted goals.
   k) Type of modalities and treatment interventions to be provided.
   l) Educational plan, including home exercises, ADL modifications.
   m) Anticipated discharge recommendations, including education of the member in a home program.

n) Date and signature of treating provider.
o) Plan of care should be reviewed at intervals appropriate to the patient and in accordance with state and third-party requirements.
p) The plan of care should clearly support why the skills of a network provider are needed as opposed to discharge to self-management or non-skilled personnel without the supervision of a network provider. If telehealth is included, the plan of care should clearly support why the skills of a network provider are needed as opposed to discharge to self-management or non-skilled personnel without the supervision of a network provider.

5. Daily Treatment Notes should include:
   a) Standard type format (i.e., SOAP) and contain the date for return visits or follow-up.
   b) Skilled treatment interventions that cannot be carried out solely by non-skilled personnel. All services and level of services must be supported by the documentation and include the clinical rationale for the treatment intervention, a time component, and goals, if needed.
   c) Assessment of patient's response or non-response to intervention and plan for subsequent treatment sessions, assessments, or updates
   d) Significant, unusual, or unexpected changes in clinical status
   e) Complete notes. Incomplete notes (for example, unsigned, undated, insufficient detail) may also result in a denial for lack of sufficient information.
6. Re-evaluations should not be routine or recurring. While there is broad consensus on the general indications for formal reevaluation of patients, there is less agreement about proposed reasons for reporting patient re-evaluations, i.e., discharge planning, on a routine/prescheduled basis, and/or in meeting regulatory requirements. An established patient evaluation is indicated if any of the following apply:
   a) The patient presents with a new condition.
   b) There is a significant or unanticipated change in symptoms or decline in functional status.
   c) Assessment of response or non-response to treatment at a point in care when meaningful clinical change can reasonably be detected.
   d) There is a basis for determining the need for change in the treatment plan/goals.
7. The re-evaluation exceeds the parameters of the typical office visit and includes the following:
   a) Updated history
   b) Subjective symptoms
   c) Physical examination findings
   d) Appropriate standardized outcome tool/measurements as compared to the previous evaluation/re-evaluation.
   e) Evidence to support the need for continued skilled care.
   f) Identify appropriate services to achieve new or existing treatment goals.
   g) Revision in Treatment Plan, i.e., updated goals
   h) Correlation to meaningful change in function
   i) Evidence of the effectiveness of the interventions provided; progress toward goals.
8. Clinic requirements for record keeping are:
   a) A financial record for each patient that includes:
      i) Date and type of service provided.
      ii) Fee for service(s)
      iii) Payment received and source of payment.
      iv) Current balance of the account

v) financial disclosure form for noncovered services

b) An appointment calendar with the name of each patient and appointment date scheduled.

c) Clinical records that must be:
   i) accessible and available to providers at the time care is rendered and at times needed to coordinate service delivery.
   ii) stored securely and not accessible to individuals who do not have legal authority to access information contained in the records.
   iii) accessible and free of charge to patients in compliance with any state and/or federal laws.

d) A process for responding to patient questions about the patient's medical records.

Regulatory, Accreditation and Resources

1. Sec. 148.107 MN Statutes
2. https://www.revisor.mn.gov/rules/4685.1110/?keyword_type=all&keyword=4685.1110#rule.4685.1110.13
3. Families and Children DHS Contract – Articles 13 and 14
4. MSHO/MSC+ DHS Contract – Articles 13 and 14
5. SNBC DHS Contract – Articles 13 and 14
6. CMS Managed Care Manual Chapter 5
7. 21st Century Cures Act

Policy History

Date	Update
05/06/2010	New document
08/02/2016	Revised document
09/22/2016	Added Fulcrum brand
09/21/2017	Annual Review
6/27/2018	Transferred from Credentialing to Network Management
06/19/2023	Revised document
10/25/2023	Policy moved from Network Management to Clinical Team
12/07/2023	Approved by Clinical Policy Committee
12/19/2023	Approved by UM Subcommittee
03/07/2024	Approved by Clinical Policy Committee
03/15/2024	Approved by Utilization Management Subcommittee
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02/04/2025	Approved by Utilization Management Subcommittee

Plain Film Radiology

Fulcrum Clinical Guidelines **Plain Film Radiology**	**Original Date: June 2018 (NIA)** **January 2018 (Fulcrum)**
Physical Medicine – Clinical Decision Making	**Last Revised Date: January 2025**
Guideline Number: CLINUM104	**Implementation Date: February 2025**

Policy Statement

Fulcrum Health, Inc. (Fulcrum) has developed this policy to support the utilization of Plain Film Radiographs for the management of spine related disorders and/or acute musculoskeletal conditions when the application of the service is consistent with a best-practice application and will achieve the best outcome for the patient.

Purpose

To apply supportive criteria for the utilization of Plain Film Radiographs for the management of acute musculoskeletal condition and spine related disorders (SRD). Fulcrum does not support the use of Plain Film Radiographs as a routine office procedure or for investigative purposes. This policy outlines the process for determining the medical necessity of plain film radiology.

Procedure

1. The decision to expose radiographs must be supported by information after a thorough clinical examination consistent with the information derived from a patient's history and presenting complaints and meet the following:
   a) Radiographic services provided must correlate with the regional diagnosis code(s).
   b) Plain Film Radiographs are not appropriate if recent films have already been exposed and are obtainable.
   c) The use of full spine radiographs for any diagnosis other than scoliosis is not considered medically necessary and will not be reimbursed.
   d) Contraindications to plain film x-rays include:
      i) Infants (0 - 36 months)
      ii) Pregnancy or possible pregnancy
      iii) Obesity, if size precludes good radiographic resolution.
      iv) Patients having positioning difficulty due to mental status or physical restrictions, which precludes good radiographic resolution.
      v) Children 3 to 18 years of age, except for investigation of suspected acute fracture, dislocation, infection, scoliosis, developmental defects, or a suspected pathology.
2. Criteria should be applied after a clinical examination and patient consultation. The following radiographic examination criteria indicate that a radiographic evaluation may be medically necessary. Plain film radiography may be supported for the initial evaluation of patients presenting with the following red flags or failure to improve with a trial of conservative treatment:
   a) Recent significant trauma that may reasonably be severe enough to cause fracture, dislocation, or milder trauma at age older than 50 years.
   b) Age older than 70 years.
   c) Osteoporosis/risk of demineralization.
   d) Focal neurologic deficit with progressive or disabling symptoms.
   e) Unexplained weight loss.
   f) History of cancer (possibility of metastatic cancer greater).
   g) Reasonable suspicion of ankylosing spondylitis or other inflammatory arthritis.

h) Intravenous drug use.
i) History of prolonged corticosteroid use (increased risk for infection, osteoporosis).
j) Unexplained fever.
k) Immunosuppression.
l) History of spinal surgery in the area to be treated with new or progressing symptoms or clinical findings.
m) History of surgery that might reasonably affect the proposed treatment.
n) Patients who are surgical or intervention candidates with persistent or progressive symptoms during or following 6 weeks of conservative management.
o) Hard or soft tissue mass noted upon palpation.
p) Prolonged unremitting symptoms with progression in severity, or prolonged unremitting symptoms of the severity to awaken the patient at night.
q) Deformity with stiffness.
r) Significant medical history (e.g., chronic inflammatory arthropathies, positive rheumatoid factor, scoliosis confirmed through appropriate history and examination, etc.) and supporting clinical findings.

3. Multiple view imaging beyond the standard A-P and Lateral view should not be performed as a routine office procedure, to support a treatment style or technique, or utilized for investigative purposes. If four or more x-ray views are required in one region, the documentation must provide clear necessity based upon relevant clinical information that supports the need for the additional oblique or flexion/extension views (including but not limited to CPT codes: 72050, 72052, 72110, 72114, 72074).

Regulatory, Accreditation and Resources

Medicare NCD & LCD

1. Article - Chiropractic Services – Medical Policy Article (A57889) (cms.gov) (01/01/2020) (IL, MN, WI, NY, CT, ME, MA, NH, RI, VT)
2. LCD - Chiropractic Services (L37387) (cms.gov) (09/29/2021) (AL, GA, TN, SC, VA, WV, NC)
3. LCD - Chiropractic Services (L37254) (cms.gov) (01/26/2023) (KY, OH)

Medicare Billing and Coding: Chiropractic Services

1. Article - Billing and Coding: Chiropractic Services (A58345) (cms.gov) (10/01/2020) (WY, CO, NM, TX, OK, AR, LA, MS, DE, DC, NJ, PA, MD)
2. Article - Billing and Coding: Chiropractic Services (A56273) (cms.gov) (07/07/20223) (IA, KS, MO, NE, IN, MI)
3. Article - Billing and Coding: Chiropractic Services (A56616) (cms.gov). (10/10/2019) (AK, GA, TN, SC, VA, WV, NC)
4. Article - Billing and Coding: Chiropractic Services (A56455) (cms.gov) (11/16/2023) (KY, OH)
5. Article - Billing and Coding: Chiropractic Services (A58412) (cms.gov) (10/01/2020) (FL, VI, PR)
6. Article - Billing and Coding: Chiropractor Services (A57914) (cms.gov) (01/01/2020) (AL, OR, WA, AZ, ND, SD, UT, WY, MT)
7. NCCI for Medicare | CMS

NCQA

1. UM 2 Element A Clinical Criteria for UM Decisions

Clinical References

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2. *Best-Practice Recommendations for Chiropractic Management of Patients with Neck Pain JMPT: Published: December 20, 2019*
3. *ICSI Guidelines, 2017*
4. *American College of Radiology Appropriateness Criteria, 2016*
5. *AMA CPT Codebook*
6. *Choosing Wisely*

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Policy History

Date	Update
4/5/2017	New Document
02/06/2018	Reviewed by Clinical Policy Committee
2/7/2018	Approved by UM Subcommittee
2/6/2019	Approved by Clinical Policy Committee
2/12/2019	Approved by UM Subcommittee
3/12/2020	Approved by Clinical Policy Committee
3/31/2020	Approved by UM Subcommittee
3/11/2021	Approved by Clinical Policy Committee
3/18/2021	Approved by UM Subcommittee
3/17/2022	Approved by Clinical Policy Committee
3/29/2022	Approved by UM Subcommittee
03/21/2023	Approved by Clinical Policy Committee
05/02/2023	Approved by UM Subcommittee
12/07/2023	Approved by Clinical Policy Committee
12/19/2023	Approved by UM Subcommittee
03/07/2024	Approved by Clinical Policy Committee
03/15/2024	Approved by Utilization Management Subcommittee
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Therapeutic Massage

Fulcrum Health, Inc	
Clinical guidelines THERAPEUTIC MASSAGE	**Original Date: January 2020 (Fulcrum)**
Physical Medicine – Clinical Decision Making	**Last Revised Date: January 2025**
Guideline Number: CLINUM118	**Implementation Date: February 2025**

Policy Statement

Fulcrum Health, Inc. (Fulcrum) has developed this policy to provide guidelines for therapeutic massage therapy to restore muscle function, reduce edema, improve joint motion, or relieve muscle spasm. The application of the guideline is used to support a best-practice approach to achieve an optimal outcome for the patient.

Please contact the health plan to obtain eligibility and health plan benefits. To the extent there is any inconsistency between this policy and the terms of the member's benefit plan or certificate of coverage, the terms of the member's benefit plan document will govern.

Scope

Fulcrum TruTouch credentialed massage therapists as well as out of network providers if permitted by the health plan.

Definitions

Therapeutic Massage - each 15 minutes, one or more areas (97124)
Effleurage, petrissage and tapotement to restore muscle function, reduce edema, improve joint motion, or relieve muscle spasm.

Effleurage: Long gliding strokes that are gentle and relaxing and are used to warm up the body and improve circulation.

Petrissage: deeper, kneading movements that are intense and designed to lengthen tight muscles and break down adhesions or thickened tissues.

Tapotement: rhythmic percussion, most frequently administered with the edge of the hand, a cupped hand or the tips of the fingers.

Myofascial Release: Myofascial Release is a safe and very effective hands-on technique that involves applying gentle sustained pressure into the Myofascial connective tissue restrictions to eliminate pain and restore motion. This essential "time element" has to do with the viscous flow and the piezoelectric phenomenon: a low load (gentle pressure) applied slowly will allow a viscoelastic medium (fascia) to elongate.

a) to restore free and unimpeded motion of all soft tissues
b) to release entrapped nerves, vasculature, and lymphatics
c) to re-establish optimal texture, resilience, and function of soft tissues.

Procedure is a service provided to increase the functional abilities in self-care, mobility, or safety.

Procedure

Therapeutic Massage may be utilized in the initial period of an episode of treatment or exacerbation of a sub-

acute or chronic condition for pain control, reduction of inflammation, or reduction of muscle spasm.

1. Therapeutic massage is clinically appropriate and/or necessary in the conservative management of neuromusculoskeletal conditions such as:
   a) Back pain,
   b) Neck and shoulder pain,
   c) Headache,
   d) Carpal Tunnel Syndrome,
   e) Osteoarthritis,
   f) Fibromyalgia, OR
   g) Limited payors may include:
      i) Some conditions associated with Type 2 diabetes mellitus.
      ii) Neoplasm pain (acute) (chronic).
2. Treatment provided is:
   a) direct one-on-one contact with the provider for 15-minute units; and
      i) 8-22 minutes: 1 Unit
      ii) 23-37 minutes: 2 Units
      iii) 38-52 minutes: 3 Units
      iv) 53-67 minutes: 4 Units
   b) improves the subjective/objective/functional deficits; and
   c) documentation clearly states:
      i) clinical rationale for treatment
      ii) specific location
      iii) objective clinical findings such as measurements of range of motion, description of muscle spasms and effect on function
      iv) subjective findings including pain ratings, pain location and effect on function.
      v) time spent performing massage therapy, and
      vi) goals of massage therapy that may include restoring muscle function, decreasing specific stiffness, reducing edema, improving joint motion, or relieving muscle spasms.
3. Therapeutic massage is considered NOT to be clinically appropriate and/or necessary when:
   a) used largely for the comfort and convenience of the patient.
   b) massage chairs, aqua massage tables and roller beds are not considered massage (LCA56566)
   c) patient safety is jeopardized by the application of the modality,
   d) treatment can safely and effectively be administered by the patient or another individual,
   e) used during a course of treatment, which continues beyond the initial period,
   f) used as the primary or sole therapy, OR
   g) used as part of the routine office protocol.

Regulatory, Accreditation and Resources

1. Fulcrum Provider Portal**:** https://fulcrumproviderportal.com
2. UCare Plan Summary Reference for UCare TruTouch
3. Quartz Medicare Advantage-TruTouch Plan Summary Reference
4. Therapeutic Massage Reimbursement Policy

Health Plan Resources:

UCare® - Coverage Policies

Medicare NCD & LCD

1. Article - Billing and Coding: Outpatient Physical and Occupational Therapy Services (A56566) (cms.gov)
2. NCCI for Medicare | CMS

NCQA

1. UM 2 Element A Clinical Criteria for UM Decisions

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ADDITIONAL RESOURCES

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Policy History

Date	Update
November 2023	New Policy
12/07/2023	Approved by Clinical Policy Committee
12/19/2023	Approved by UM Subcommittee
03/07/2024	Approved by Clinical Policy Committee
03/15/2024	Approved by Utilization Management Subcommittee
01/23/2025	Approved by Clinical Policy Committee
02/04/2025	Approved by Utilization Management Subcommittee

Measurable Progressive Improvement

Fulcrum Health, Inc	
Clinical guidelines **Measurable Progressive Improvement**	**Original Date: June 2018**
Physical Medicine – Clinical Decision Making	**Last Revised Date: January 2025**
Guideline Number: CLINUM123	**Implementation Date: February 2025**

Policy Statement

Outcome measures and/or pre-determined treatment goals that are specific, measurable, and/or functional must be used with each patient. These goals and outcome measures must be clearly defined in the patient record to ascertain the amount or degree of change over time. The documentation must also provide evidence of lasting, sustainable progress with treatment.

Purpose

This policy will be used to provide minimal clinical thresholds using specific, measurable, and functional treatment goals and/or outcome measures in the determination of improved, lasting, and sustained outcomes. These thresholds will assist in medical necessity reviews of billed clinical services by network practitioners. It is an expectation that all patients receive care/services from a licensed clinician. All appropriate supporting documentation, including recent pertinent office visit notes, laboratory data, and results of any special testing must be provided. If applicable: All prior relevant imaging results and the reason that alternative imaging cannot be performed must be included in the documentation submitted.

Definitions

Treatment Goals: Determined with the patient and clinician at the initial encounter for each episode of care. Unique for each patient's clinical presentation based on the evaluation/examination findings, outcome assessment tool results, and personal preferences.

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

Specific, Measurable, and Reasonably Achievable Goals:
Clearly defined goals of treatment that allow measurement of the amount and/or degree of meaningful change in function, pain, or other quality of life measures over time. These goals are often determined by the use of functional outcome assessment tools, as defined in Clinical Guideline, Record Keeping and Documentation Standards.

Outcome Measures: Objective, measurable assessments by the clinician to determine patient progress with treatment. The use of standardized tests and measures at the onset of care establishes the baseline status of the patient, providing a means to quantify change in the patient's functioning. Outcome measures, along with other standardized tests and measures used throughout the episode of care, as part of periodic reexamination, provide information about whether predicted outcomes are being realized. Outcomes measurement refers to the systematic collection and analysis of information that is used to evaluate the efficacy of an intervention. Systematic collection means that data are gathered at multiple time points using the same methods or instruments. Analysis refers to the process of condensing and examining the data to identify meaningful trends or changes. The World Health Organization defines an outcome measure as a "change in the health status of an individual, group or population which is attributable to a planned intervention or series of interventions…."[82]

Lasting, Sustainable Progress: Documentation must provide evidence to support that progress made by the patient has been maintained at a reasonable level over a reasonable period of time.

Minimally Clinically Important Change (MCIC): The smallest change in the outcome assessment score that the patient perceives as beneficial, i.e., clinically meaningful improvement.

Minimal Detectable Change (MDC): The minimal detectable change is the smallest change in score than can be detected beyond random error and is dependent upon sample distribution.

Minimal Clinically Important Difference (MCID): MCID is the smallest change in an outcome that a patient would identify as important.

Maximum Therapeutic Benefit (MTB)

Maximum Therapeutic Benefit (MTB) is determined following a sufficient course of care, where demonstrable improvement would be expected in a patient's health status and one or more of the following are present:

- The patient has returned to pre-clinical/pre-onset health status.
- Meaningful improvement has occurred; however, there is no basis for further meaningful improvement.
- Meaningful improvement has occurred and there is no basis for further in-office treatment.
- The patient no longer demonstrates meaningful clinical improvement, as measured by standardized outcome assessment tools.
- Meaningful improvement, as measured by standardized outcome assessment tools, has not been achieved.
- There is insufficient information documented in the submitted patient record to reliably validate the response to treatment.

It is the responsibility of the treating practitioner to maintain a patient record that includes periodic measures of treatment response by employing valid, reliable, and relevant outcome assessment tools. Further, it is the responsibility of the treating practitioner to include sufficient clinical documentation, so that a peer reviewer can render a reasonable determination on baseline functional status and/or treatment response. Also, meaningful improvement can occur only when there is a potential for MCIC. When progress towards goals is such that outcome measures approximate normative data for asymptomatic populations or are indicative of mild deficits, which can typically be managed through home exercise or other self-care, then a determination of MTB is appropriate. Most individuals can expect to notice measurable improvement in pain and/or disability within 2 to 6 weeks after beginning treatment. If improvement has not occurred with 6 weeks of treatment, it is highly unlikely that continuing treatment will be helpful. When initial improvement did occur, many studies showed no additional lasting improvement beyond 6 to 12 weeks of treatment. Most flare-ups resolve quickly – within a few days to 3 weeks. The timelines for improvement may not be applicable to some types of post-surgical care.[83-91]

Patient Acceptable Symptom State (PASS): PASS is defined as the point at which the patient considers themselves well, recovered, and satisfied with treatment.

Procedure

1. Acceptable Thresholds of Measurable Improvement

Meaningful clinical change (Minimal Clinically Important Change-MCIC; Minimal Clinically Important Differences-MCID; Minimal Detectable Change-MDC; Small Meaningful Change - SMC) has been calculated for most common standardized outcome assessment tools. The application of valid and reliable outcome assessment tools in the management of neuromusculoskeletal disorders is generally considered as "best practice."

2. To make a valid, reliable determination of meaningful progress toward goals (MCIC) and/or Maximum Therapeutic Benefit (MTB), it is essential that the record include a relevant standardized outcome assessment tool. Progress towards goals should be assessed at predetermined time periods and supported by anticipated meaningful clinical change based on treatment plan goals. Typically, recovery patterns for neuromusculoskeletal conditions involving the low back, neck, and headache disorders show that > 50% of the overall improvement with care occurs within 4 - 6 weeks. When patients are categorized via predictive modeling, the percentage of those showing significant improvement within 6 weeks rises considerably. [1-4] Studies have consistently shown that short-term treatment response is predictive of long-term outcomes. McGorry showed that exacerbations of LBP resolved within a few days (52%); within a week (16%); within two-three weeks (26%); even severe flare-ups usually resolved within nine days.[5] After a review of the scientific evidence, Fulcrum has concluded all practitioner records must evaluate and document whether treatment is resulting in progressive and sustained improvement.
3. The practitioner records must demonstrate clear, specific, and measurable improvement in the patient's pain and function every two weeks or at regular intervals as appropriate for the documented condition, as measured by one or more of the following examples of methods for each anatomic region. If no functional tool is available for the patient's condition, it is expected the practitioner will develop specific, measurable, and reasonably achievable goals:

- 6-Minute Walk test (6MWT) for Older Adults[6,7]
    - SMC - Older people with limited mobility[8]: 21 m (69 feet)
    - SMC - Older people with stroke[8]: 22 m (72 feet)
    - MDC - Alzheimer's Disease[8,9]: 33.5 m (110 feet)
    - Either hip OA or knee OA that later received a total joint replacement[10]: 61.24m
- Activities of Daily Living Scale of the Knee Outcome Survey
    - 10 - 30% reduction in the global score
    - MCID = 7.1%[11]
- Activity-Specific Balance Confidence Scale (ABC)
    - SMC – older adults[12] = 7 points
    - MDC - Parkinson's Disease[13,14] = 11 – 13%
    - MDC – CVA[15,16] = 14%
    - MCID – Vestibular Disorders = 18.1%[17]
- Berg Balance Scale
    - MDC = 6.2 - 6.5 points[18,19]
    - MDC – older adults[20] = 10.5 points
    - MDC - Parkinson's Disease[14] = 5 points
    - MDC – chronic stroke[21] = 2.7 points
    - MCID – subacute stroke (assisted walking) – 5 points[22]
    - MCID – subacute stroke (unassisted walking) – 4 points[22]
- Bournemouth – Back Questionnaire
    - A change of 26 points in acute conditions and 18 points in subacute/chronic

conditions.[23] It is recommended that the Bournemouth be used at baseline and for every 2 - 4 weeks or 6 - 12 visits thereafter within the treatment program to measure progress.

- Bournemouth – Neck Questionnaire
  - A change of 13 points or 36% is considered clinically significant improvement.[24] It is recommended that the Bournemouth be used at baseline and for every 2 - 4 weeks or 6 - 12 visits thereafter within the treatment program to measure progress.
- Bruininks-Oseretsky Test of Motor Proficiency, 2nd Edition (BOT-2)[25]
  - Minimal Detectable Change (MDC):
    - Children aged 3-6 years with intellectual disability
    - MDC=7.4 (BOT-2-SF Standard Scores)Children aged 4-21 years with intellectual disability
      - MDC=4.2 (aged 4-12 years) / 7.4 (aged 13-21 years) (standard scores
- Disability of Arm, Shoulder, and Hand (DASH, qDASH)[26-28]
  - DASH MCID = 11-15 points
  - QuickDASH MCID = 6.8-15 points
- Dizziness Handicap Inventory
  - MDC = 17.18 points[29]
- Dynamic Gait Index
  - MDC = 2.9 points[18]
- Falls Self Efficacy Scale/Falls Efficacy Scale-International (FES-I)[30-32]
  - MDC - vestibular disorders[30] = 8.2 points
  - MDC - hip fracture[32] = 17.7 points
- Foot and Ankle Ability Measures (FAAM)[33,34]
  - ADL subscale MCID = 8 points
  - Sport subscale MCID = 9 points
- Fear Avoidance Belief Questionnaire (FAB-Q)[35]
  - MCIC – following arthroscopic subacromial decompression[36] = -5.0
  - MDC – low back pain = -5.4
- Functional Gait Assessment
  - MCID = 4 points[37]
  - MCID – Vestibular Disorders = 4 points[17]
- Functional Rating Index
  - A 10% absolute change represents minimal clinically important change[38]
  - MCID = 8.4%
  - It is recommended that for acute and subacute conditions the FRI be used at baseline and every 1 week or 3 visits thereafter. It is recommended that for chronic conditions the FRI be used at baseline and every 2 weeks or 6 visits thereafter. If the score does not improve by at least 10% (absolute change) in any two successive two-week periods, you should pursue a change in management.
- FOTO or Functional Status (FS) measure[39,40]:
  - The MCII (Minimally Clinically Important Improvement) and MDC (Minimal Detectable Change) are stated on the assessment report. For significant, minimal improvement, the patient status should increase by the MDC value. FOTO summary report is available upon request.

- Gait Speed for Adults
  - Small meaningful change[8] = .5m/sec
  - Substantial meaningful change[8] = .10m/sec
  - Meaningful change for those with stroke undergoing rehab = .175 m/sec[41]
  - MDC – heart failure[42] = 0.05 m/s
  - MCID – heart failure[42] = 0.05 – 0.12 m/s
  - MDC – joint pain and fractures[43] = 0.08 m/s
  - MCID – joint pain and fractures[43] = 0.1 m/s
  - MCID – Vestibular Disorders = 0.09 m/s[17]
- Global Rating of Change (GRoC)[44-46] (‡See Note below)
  - MDC 0.45 points on 11-point scale
  - MCIC 2 points on 11-point scale
- Gross Motor Function Measure-66 (GMFM-66)[47]
  - Clinically meaningful improvement = 1.58
- Headache Disability Inventory (HDI)
  - Authors of the index have determined that a decrease of 29 points or more is considered clinically significant.[48]
- Keele STarT Back Screening Tool
  - No MDC or MCID established
  - Low-, Medium- and High-risk categories established for subscales and overall score
- Knee Injury and Osteoarthritis Outcome Score (KOOS)[49,50]
  - MDCs of KOOS subscales for younger individuals = 14.3 – 19.6 points
  - MDCs of KOOS subscales for older individuals = ≥20 points
  - MCID - post arthroscopic meniscal repair = 12.3 for symptoms, 11.8 for pain, 11.4 for activities of daily living (ADL) and 16.9 for quality of life (QOL)[51]
  - MCID - post total knee arthroplasty = 13.5 for pain, 15.2 for function and 8.0 for quality of life (QOL)[52]
- Knee Outcome Survey
  - MDC = 9 points
  - MCID = 7 points
- Lower Extremity Functional Scale (LEFS) MDC = 9 points
  - MCID = 8 – 9.4 points.[53,54] It is recommended that the LEFS be used at baseline and for every 2 - 4 weeks or 6 - 12 visits thereafter within the treatment program to measure progress.
- Lysholm Knee Rating System
  - MDC = 10 points
- Neck Disability Index
  - MDC = 10 – 20%.[55,56] It is recommended that the Neck Disability Index be used at baseline and for every 2 weeks thereafter within the treatment program to measure progress. A score of 0% - 20% represents a minimal disability. Usually no treatment is indicated, apart from advice on posture, physical fitness, and diet. Patients often do not score the Neck Disability items as zero, once they are in treatment. The practitioner should consider the patient's prior level of function when goal writing (for example, if the patient's prior level

of function would place them in the minimal disability category, their goal should not be to obtain a zero score).

- Numeric Pain Rating Scale (NPRS)
  - MCID = 2 points[57]
  - MCID – spinal cord injuries = 1.6 points[58]
- Oswestry Disability Index
  - The Minimal Important Change is 10 points or a 20% improvement.[59] It is recommended that the Oswestry Disability Index be used at baseline and for every 2 weeks thereafter within the treatment program to measure progress. A score of 0% -20% represents a minimal disability. Usually no treatment is indicated, apart from advice on lifting, sitting posture, physical fitness, and diet. Patients often do not score the Oswestry items as zero once they are in treatment. The practitioner should consider the patient's prior level of function when goal writing (for example, if the patient's prior level of function would place them in the minimal disability category, their goal should not be to obtain a zero score).
- Pain Disability Index
  - A decrease of 8.5 - 9.5 points is considered clinically important in individuals with chronic back pain[60]
- Patient Specific Functional Scale (PSFS)[61-64]
  - MDC (90% CI) for average score = 2 points
  - MDC for older adults = 2.8[65]
  - MDC (90% CI) for single activity score = 3 points.[64] It is recommended that the PSFS be used at baseline and for every 2 - 4 weeks or 6 - 12 visits thereafter within the treatment program to measure progress.
  - MCID in individuals with knee dysfunction, cervical radiculopathy, or chronic low back pain = 2.0 – 3.0 points[62,63]
- Peabody Developmental Motor Scales-2nd Edition (PDMS-2)[66]
  - MDC for preschoolers with intellectual disabilities[67] = 7.76
  - MCID for preschoolers with intellectual disabilities[67] = 8.39
- Pediatric Balance Scale[68]
  - MDC:
    - CP total 1.59
    - Static 0.79
    - Dynamic 0.96
  - MDIC:
    - CP total 5.83
    - Static 2.92
    - Dynamic 2.92
- Roland-Morris Disability Questionnaire
  - MDC = 7.6 points[69] or a 30% improvement from baseline.[59] It is recommended that the RMDQ be used at baseline and for every 2 - 4 weeks or 6 - 12 visits thereafter within the treatment program to measure progress.
- Shoulder Pain and Disability Index
  - The smallest detectable change is 19.7 points, and the minimal important change is 20 points.[70] It is recommended that the SPADI be used at baseline and for every 2 - 4 weeks or 6 - 12 visits thereafter within the treatment program to measure

progress.

- Simple Shoulder Test (SST)
  - MCID
    - anatomic total shoulder arthroplasty (aTSA) 1.6[71]
    - ream-and-run arthroplasty (R&R) 2.6[71]
    - reverse total shoulder arthroplasty (rTSA) 3.7[71]
- Timed Up and Go (TUG)[72]
  - Cut-off score of 13.5 sec or longer is predictive of falls; however, the Timed Up and Go test has limited ability to predict falls in community dwelling elderly and should not be used in isolation to identify individuals at high risk of falls in this setting.[73]
  - MDC – Alzheimer disease[72] = 4.09 sec
  - MDC – chronic stroke[72,74] = 2.9 sec
  - MDC – Parkinson's disease[14,72,75,76] = 3.5 – 11 sec
  - MDC – Total hip arthroplasty = >1.62 seconds[77]
  - MCID – Post lumbar degenerative disc disease surgery = 2.1 seconds (or TUG z score change of 1.5)[78]
- Tinetti (POMA)
  - MDC= 5 Points[79]
- Visual Analog Scale (VAS) scores
  - Minimum of a 2 point change on a 0-10 pain scale
  - MCID – post-operative hand surgery = 1.6[80]
- Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC)[81]
  - After TKA- MCID=10, MIC (minimal important change) = 17
  - MCID for LE OA= changes of 17-22% of baseline scores

The records must compare baseline measures to updated measures and document progress toward measurable goals as defined in Clinical Guideline, Plan of Care.

‡NOTE: Questionable Outcome tool: Global Rating of Change (GRoC)

Further work is needed to determine the true value of the GRoC as an outcome measure and in turn as an anchor measure. Several key points have been identified:

- There is fluctuant temporal stability of the GRoC from week to week.
- There is poor correlation between the GRoC and functional measures.
- The GRoC is only correlated to functional measures up to 3 weeks.

Clinical Resources

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Policy History

Date	Update
November 2023	New Policy
12/07/2023	Approved by Clinical Policy Committee
12/19/2023	Approved by UM Subcommittee
03/07/2024	Approved by Clinical Policy Committee
03/15/2024	Approved by Utilization Management Subcommittee
01/23/2025	Approved by Clinical Policy Committee
02/04/2025	Approved by Utilization Management Subcommittee

Outpatient Habilitative Physical and Occupational Therapy

Fulcrum Clinical Guidelines **Outpatient Habilitative Physical and Occupational Therapy**	**Original Date: November 2015 (NIA)**
Physical Medicine – Clinical Decision Making	**Last Revised Date: January 2025**
Guideline Number: CLINUM119	**Implementation Date: February 2025**

Policy Statement

Habilitative physical and occupational therapy services may or may not be covered by all clients of this organization. If the service is covered, it may or may not require prior authorization. These guidelines apply to all markets and populations, including teletherapy, contracted with this organization through the corresponding state health plans unless a market-specific health plan has been developed. Services may be covered when provided for the end result of achieving age-appropriate growth/development; correcting or improving a physical condition; or helping a patient acquire, maintain, or regain functional skills for successful participation in everyday activities. These services must be provided by a skilled and licensed therapy practitioner and in a manner that is in accordance with accepted standards of practice for discipline-specific therapies. It must also be clinically appropriate in amount, duration, and scope to achieve their purpose and considered effective treatment for the current injury, illness or condition.

Habilitative physical and occupational therapy should meet the definitions and be provided in a clinic, office, home, or in an outpatient setting and be ordered by either a primary care practitioner or specialist unless otherwise directed by state law or statute.

Fulcrum will review all requests resulting in adverse determinations for Medicaid members for coverage under federal Early and Periodic Screening, Diagnostic and Treatment (EPSDT) guidelines.[1,2]

Definitions:

Habilitative Physical or Occupational Therapy

Treatment provided by a state-regulated physical or occupational therapist designed to help a person learn, obtain, maintain, prevent deterioration of or improve age-appropriate skills and functioning for daily living.[4,14] These skills may have never been present, lost, or impaired due to a congenital, genetic, or early acquired condition. There must be measurable improvement and progress towards functional goals within an anticipated timeframe toward a patient's maximum potential. Treatment may also be appropriate in an individual with a progressive disorder when it has the potential to prevent the loss of a functional skill or enhance the adaptation to such functional loss. Ongoing treatment is not appropriate when a steady state of sensorimotor functioning has yielded no measurable functional progress.

Rehabilitative Physical or Occupational Therapy: Treatment provided by a state-regulated physical or occupational therapist designed to help a person recover from an acute injury or exacerbation of a chronic condition that has resulted in a decline in functional performance. The specific impact of injury or exacerbation on the The patient's ability to perform in their everyday environment must be supported by appropriate tests and measures and clinical observations. Services must be provided within a reasonable time frame (frequency/duration) to restore lost function or to teach compensatory techniques if full recovery of function is not possible.

Maintenance Program: A program established by a licensed therapist that consists of activities and/or mechanisms that will assist the patient in optimizing or maintaining the progress he or she has made during

therapy or to prevent or slow further deteriorations due to a disease or illness.

Medical Necessity: Reasonable or necessary services that require the specific training, skills, and knowledge of a physical or occupational therapist in order to diagnose, correct, or significantly improve/optimize as well as prevent deterioration or development of additional physical and mental health conditions. These services require a complexity of care that can only be safely and effectively performed by or under the general supervision of a skilled therapist. Services shall not be considered reasonable and medically necessary if they can be omitted without adversely affecting the member's condition or the quality of medical care. A service is also not considered a skilled therapy service merely because it is furnished by a therapist or by a therapy assistant under the direct or general supervision, as applicable, of a therapist. If a service can be self-administered or safely and effectively carried out by an unskilled person, without the direct supervision of a therapist, as applicable, then the service cannot be regarded as a skilled therapy service even though a therapist actually rendered the service. Similarly, the unavailability of a competent person to provide a non-skilled service, notwithstanding the importance of the service to the patient, does not make it a skilled service when a therapist renders the service.

Activities of Daily Living (ADLs): Essential activities oriented toward taking care of one's own body (also referred to as basic and/or personal activities of daily living). Such activities are fundamental to living in a social world as well as enabling basic survival and well-being. Specific examples include bathing/showering, toileting, dressing, swallowing/eating, feeding, functional mobility, personal device care, personal hygiene/grooming, and the functional mobility necessary to perform these activities. The initial evaluation and corresponding plan of care should document baseline impairments as they relate to ADL performance deficits with targeted functional outcomes/goals that are measurable, sustainable, and time specific. Subsequent plans should clearly document functional progress toward attainment of these goals in perspective to the patient's potential ability as well as skilled interventions used to target functional outcomes.[3,5,22]

Functional Mobility Skills: They are considered necessary activities of daily life such as ambulation, transfers, and fine motor skills. The initial plan of care documents baseline impairments as they relate to functional skills with specific goals developed that are specific, measurable, attainable, relevant, and time-based (SMART format). Subsequent plans of care document progress toward attainment of these goals in perspective to the patients' potential ability.

Sensory Integration Disorder: Sensory integration involves perceiving, modulating, organizing, and interpreting internal sensations from within the body as well as external sensations from the surrounding environment to optimize occupational performance and participation. Deficits in sensory integration can pose challenges in performing activities of daily living, in addition to development, learning, playing, working, socializing, and exhibiting appropriate behavior. Differences in interpretation of stimuli can impact motor skills and coordination, further limiting engagement and participation. Sensory processing difficulties can occur across the lifespan. Sensory integrative therapy and evidence-based interventions provide neuroscience- based, cognitive, and/or behavioral approaches that support successful adaptive responses.[23]

Procedure:

Physical and/or occupational therapy evaluation and treatment services are considered medically necessary when the following criteria are met:

1. Have written referral from primary care practitioner or other non-physician practitioner (NNP) if required by state guidelines.
2. Physical and occupational therapy initial evaluations and re-evaluations that include patient history such as

recent illness, injury, or disability along with diagnosis and date of onset and/or exacerbation of the condition. Prior and current level of function as well as identification of any underlying factors that have impacted current functional performance must also be noted.[3-5]

3. Formal testing must be age-appropriate, norm-referenced, standardized, and specific to the therapy provided. Test scores should meet the following criteria to establish presence of a motor or functional delay. Notes should document the following to establish the presence of delays or deficits:
   a) The following methods are generally accepted measures that may be considered to support a significant delay:
      i) Standardized scores at or below the 10th percentile in at least one subtest area for the patient's age.[6]
      ii) Standardized scores greater than or equal to 1.5 standard deviations below the mean in at least one subtest area for the patient's age.[1,2,6-10]
      iii) Functional delays may be established by 25% or greater deficit in age equivalency as indicated by established general guidelines of functional assessments or specific criterion-referenced tests or profiles.[1,2,6-8,11]
   b) While standardized testing is preferred, scores alone may not be used as the sole criteria for determining a patient's medical need for skilled intervention. Test information must be linked to difficulty with or inability to perform everyday tasks.
4. In the absence of standardized testing or when test scores show skills within normal ranges despite functional deficits, the documentation must include detailed clinical observations and objective data to document the degree and severity of the condition, in order to support the medical need for skilled services. A caregiver interview/questionnaire can also support the request.
5. Any time standardized testing cannot be completed, the documentation must clearly state the reason formal testing could not be done.
   a) If the member's medical or cognitive status does not allow for formal testing, the documentation must clearly state the reason formal testing could not be completed.
   b) In the absence of standardized testing or when test scores show skills within normal ranges though functional deficits are present, the report must include detailed clinical observations of current skill sets, parent interview/questionnaire and/or informal assessment supporting functional mobility/ADL deficits and the medical need for skilled services. The documentation must clearly state the reason formal testing could not be completed.
   c) Orthopedic diagnoses not related to functional delay including torticollis and gait deviations such as in-toeing or toe walking should include appropriate tests and measures specific to the deficit and the therapy provided.
   d) In the case of feeding difficulties, the notes must clearly indicate a functional feeding delay because of underlying impairments.
      i) This may include gagging/choking, oral motor or upper extremity coordination deficits, or maladaptive behaviors due to food intolerance/aversion preventing adequate oral intake that contribute to malnutrition or decreased body mass index.
      ii) Fine motor and/or sensory testing, as well as detailed clinical observations of oral motor skills, should also be included in the documentation if functional feeding delays are a result of these component parts of the overall task.
      iii) Parent report of limited food choices is not adequate to support the medical need for feeding therapy.
      iv) There must also be evidence of ongoing progress and a consistent home regimen to facilitate carry-over of target feeding skills; strategies; and education of patient, family, and caregivers.
      v) Therapies for picky eaters who can eat and swallow normally meeting growth and

developmental milestones, eat at least one food from all major food groups (protein, grains, fruits, etc.) and more than 20 different foods is not medically necessary.

6. Re-evaluations must be performed annually at a minimum to show progress, support ongoing delays or functional deficits and medical necessity for continued services. Re- evaluations should include updated formal testing that is age-appropriate, norm- referenced, standardized, and specific to the type of therapy provided (see Record Keeping and Documentation Standards, Fulcrum's *RECORD KEEPING AND DOCUMENTATION STANDARDS: PHYSICAL MEDICINE*) for additional information regarding re-evaluation requirements). More frequent objective measures may be needed to show progress and support ongoing delays (see progress note section below).
7. Retesting with norm-referenced standardized test tools for re-evaluations must occur yearly and may occur every 180 days. Tests must be age appropriate for the child being tested and providers must use the same testing instrument as used in the initial evaluation. If reuse of the initial testing instrument is not appropriate, i.e., due to a change in member status or restricted age range of the testing tool, the provider should explain the reason for the change.
8. When skilled services are also being provided by other community service agencies and/or school systems, the notes must show how the requested services are working in coordination with these agencies and not duplicating services. The extent or lack of these additional services must be indicated in the documentation.
9. Measurable short and long-term functional goals should be SMART: specific, measurable, attainable, relevant, and timed. Individualized targeted outcomes that are linked to functional limitations outlined in the most recent evaluation/assessment.[12] These goals should include the date in which the goal was established, as well as the date in which the goal is expected to be met. Goals of intervention should target the functional deficits identified by the skilled therapist during the assessment and promote attainment of age-appropriate developmental milestones, functional mobility and/or ADL skills appropriate to the patient's age and circumstances. [13]
    a) Although identified as component parts of participation, underlying factors, performance skills, client factors or the environment should not be the targeted outcome of long-term goals.
    b) In like manner, underlying factors such as strength, range of motion, or cognition should not be the sole focus of short-term goals.14 When documenting interventions, an explicit connection must be made to what participation outcome the intervention will target.
10. Intervention selections must be evidence-based, chosen to address the targeted goals, and representative of the best practices outlined by the corresponding national organizations.[3,5]
    a) The ultimate focus of interventions[15] must be to promote motor learning or relatively permanent differences in motor skill capability that can be transferred and generalized to new learning situations.
11. The plan of care must include goals detailing type, amount, duration, and frequency of therapy services required to achieve targeted outcomes. The frequency and duration must also be commensurate with the patient's level of disability, medical and skilled therapy needs as well as accepted standards of practice while reflecting clinical reasoning and current evidence.[16]
12. Frequency and duration of skilled services must also be in accordance with the following:
    a) Intense frequencies (3x/week or more, for a short duration of 2-6 weeks[17]) will require additional documentation and testing supporting a medical need to achieve an identified new skill or recover function with specific, achievable goals within the requested intensive period.[16] Details on why a higher frequency is more beneficial than a moderate or low frequency must be included. Higher frequencies may be considered when delays are classified as severe as indicated by corresponding testing guidelines used in the evaluation. More intensive frequencies may be necessary in the acute phase; however, progressive decline in frequency is expected within a reasonable time frame.

i) On a case-by-case basis, a high frequency requested for a short-term period (4 weeks or less) which does not meet the above criteria may be considered with all of the following documentation:
   (1) Letter of medical need from the prescribing provider documenting the member's rehabilitation potential for achieving the goals identified.
   (2) Therapy summary documenting all of the following:
      (a) Purpose of the high frequency requested (e.g., close to achieving a milestone)
      (b) Identification of the functional skill which will be achieved with high frequency therapy, and
      (c) Specific measurable goals related to the high frequency requested and the expected date the goal will be achieved.

b) Moderate frequency (2x/week) should be consistent with moderate delays as established in the general guidelines of formal assessments used in the evaluation. Therapy provided two times a week may be considered when documentation shows one or more of the following:
   i) The member is making very good functional progress toward goals.
   ii) The member is in a critical period to gain new skills or restore function or is at risk of regression.
   iii) The licensed therapist needs to adjust the member's therapy plan and home program weekly or more often than weekly based on the member's progress and medical needs.
   iv) The member has complex needs requiring ongoing education of the responsible adult.

c) Low frequency (at or less than 1x/week). Therapy provided one time per week or less may be considered when the documentation shows one or more of the following[16]:
   i) The member is making progress toward their goals, but the progress has slowed, or documentation shows the member is at risk of deterioration due to the member's medical condition.
   ii) The licensed therapist is required to adjust the member's therapy plan and home program weekly to every other week based on the member's progress.
   iii) Every other week therapy is supported for members whose medical condition is stable, they are making progress, and it is anticipated the member will not regress with every other week therapy.
   iv) Frequencies less than every other week may be appropriate for those children who cannot yet tolerate more frequent therapy sessions. They may also have needs that are addressed on a periodic basis as part of comprehensive management in a specialty clinic. Occasional consultation may be appropriate to ensure gains continue, to address emerging concerns, or to help order equipment and train in its use.

d) All requested frequencies must be supported by skilled treatment interventions regardless of level of severity of delay.[18]

13. Documentation should clearly reflect why the skills of a therapist are medically necessary. There must be evidence as to whether the services are considered reasonable, effective treatments requiring the skills of a therapist or whether they can be safely and effectively carried out by non-skilled personnel without the supervision of qualified professionals.
14. Clinical updates that include current objective measures, progress towards goals, and requested frequency and duration of care are expected at regular intervals or when additional care is requested. Documentation should include:
    a) The patient's current level of function, any conditions that are impacting his/her ability to benefit from skilled intervention.
    b) Objective measures of the patient's overall functional progress relative to each treatment goal as well as a comparison to the previous progress report.[19] Outcomes should assist in functional skill acquisition that is sustained over time.

c) Skilled treatment techniques that are being utilized in therapy as well as the patient's response to therapy and why there may be a lack thereof.
d) An explanation of any significant changes in the plan of care and clinical rationale for why the ongoing skills of a PT/OT are medically necessary.
e) In the case of maintenance programs, clear documentation of the skilled interventions rendered and objective details of how these interventions are preventing deterioration or making the condition more tolerable must be provided. The notes must also clearly demonstrate that the specialized judgment, knowledge, and skills of a qualified therapist (as opposed to a non- skilled individual) are required for the safe and effective performance of services in a maintenance program.

15. Maintenance Level/Prevent Deterioration
    a) This frequency level (e.g., every other week, monthly, every 3 months) is used when the therapy plan changes very slowly, the home program is at a level that may be managed by the member or the responsible adult/caregiver, or the therapy plan requires infrequent updates by the skilled therapist. Documentation must show that the habilitative plan of care has ended, and a new plan of care established for maintenance.
    b) Goals in the plan of care must be updated to reflect that care is focused on maintaining the current level of functioning and preventing regression, rather than progressing or improving function.
    c) A maintenance level of therapy services may be considered when a member requires skilled therapy for ongoing periodic assessments and consultations and the member meets one of the following criteria:
        i) Progress has slowed or stopped, but documentation supports that ongoing skilled therapy is required to maintain the progress made or prevent deterioration.
        ii) The submitted documentation shows that the member may be making limited progress toward goals or that goal attainment is extremely slow.
        iii) Factors are identified that inhibit the member's ability to achieve established goals (e.g., the member cannot participate in therapy sessions due to behavior issues or issues with anxiety).
        iv) Documentation shows the member and the responsible adult have a continuing need for education, a periodic adjustment of the home program, or regular modification of equipment to meet the member's needs. Clear documentation of the skilled interventions rendered and objective details of how these interventions are preventing deterioration or making the condition more tolerable must be provided. The notes must also clearly demonstrate that the specialized judgment, knowledge, and skills of a qualified therapist (as opposed to a non-skilled individual) are required for the safe and effective performance of services in a maintenance program.
16. If the patient is not progressing, then documentation of a revised treatment plan is necessary. Discontinuation of therapy may be considered in one or more of the following situations:
    a) The patient no longer demonstrates functional impairment or has achieved goals set forth in the treatment plan or plan of care.
    b) The patient has returned to baseline function.
    c) The patient can continue therapy with a home treatment program and deficits no longer require a skilled therapy intervention and, for members who are 20 years of age and younger only, maintain status.
    d) The patient has adapted to impairment with assistive equipment or devices.
    e) The patient is able to perform ADLs with minimal to no assistance from caregiver.
    f) The patient has achieved maximum functional benefit from therapy in progress or will no longer

benefit from additional therapy.

g) The patient r is unable to participate in the treatment plan or plan of care due to medical, psychological, or social complications; and responsible adult has had instruction on the home treatment program and the skills of a therapist are not needed to provide or supervise the service.
h) Testing shows the member no longer has a developmental delay.
i) Plateau in response to therapy/lack of progress towards therapy goals.
j) Non-compliance due to poor attendance by the patient or responsible adult, non-compliance with therapy and home treatment program.
k) The patient has achieved the maximum therapeutic value of a treatment plan, no additional functional improvement is apparent or expected to occur, and the provision of services for a condition cease to be of therapeutic value.

17. It is expected that a discharge plan, with the expected treatment frequency and duration, must be included in the plan of care. The discharge plan must indicate the plan to wean services once the patient has attained their goals, if no measurable functional improvement has been demonstrated, or if the program can be carried out by caregivers or other non-skilled personnel.
18. Development of an age-appropriate home regimen to facilitate carry-over of targeted skills and strategies as well as patient, family, and caregiver education in home exercises and self-monitoring should be evident in the documentation. Indication of compliance of the home regimen should be documented to show maximum benefit of care.
19. For patients no longer showing functional improvement, a weaning process of one to two months should occur. If the patient shows signs of regression in function, the need.
for skilled physical or occupational therapy can be re-evaluated at that time. Periodic episodes of care may be needed over a lifetime to address specific needs or changes in condition resulting in functional decline.[20,21]

Regulatory, Accreditation and Resources

Fulcrum Provider Portal: https://fulcrumproviderportal.com

Medicare NCD & LCD

1. Article - Billing and Coding: Outpatient Physical and Occupational Therapy Services (A56566) (cms.gov)
2. Article - Billing and Coding: Outpatient Physical and Occupational Therapy Services (A57067) (cms.gov)
2. NCCI for Medicare | CMS
3. Article - Billing and Coding: Home Health Occupational Therapy (A53057) (cms.gov)
4. Article - Billing and Coding: Home Health Physical Therapy (A53058) (cms.gov)
5. Article - Billing and Coding: Outpatient Occupational Therapy (A53064) (cms.gov)
6. Article - Billing and Coding: Outpatient Physical Therapy (A53065) (cms.gov)
7. Article - Billing and Coding: Physical Therapy - Home Health (A57311) (cms.gov)
8. LCD - Physical Therapy - Home Health (L33942) (cms.gov)

NCQA

1. UM 2 Element A Clinical Criteria for UM Decisions

Clinical Resources

1. Early and Periodic Screening, Diagnostic and Treatment (EPSDT) – A Guide for States. Coverage in the Medicaid Benefit for Children and Adolescents (2014). Centers for Medicare and Medicaid Services. December 2, 2022. https://www.medicaid.gov/sites/default/files/2019-12/epsdt_coverage_guide.pdf
2. Early and Periodic Screening, Diagnostic, and Treatment. Centers for Medicare and Medicaid Services. Updated June 29, 2022. Accessed December 2, 2022. https://www.medicaid.gov/medicaid/benefits/early-and-periodic-screening-diagnostic-and- treatment/index.html
3. Occupational Therapy Practice Framework: Domain and Process (3rd Edition). *The American Journal of Occupational Therapy*. 2014;68(Supplement_1):S1-S48. doi:10.5014/ajot.2014.682006

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14. Amini D, Furniss J. The Occupational Therapy Practice Framework: A Foundation for Documentation. American Occupational Therapy Association (AOTA). Updated October 2018.
    Accessed August 4, 2022. https://www.aota.org/~/media/Corporate/Files/Publications/CE- Articles/CE-Article-October-2018.pdf
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ADDITIONAL RESOURCES

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Policy History

Date	Update
November 2023	New Policy
12/07/2023	Approved by Clinical Policy Committee
12/19/2023	Approved by UM Subcommittee

03/07/2024	Approved by Clinical Policy Committee
03/15/2024	Approved by Utilization Management Subcommittee
01/23/2025	Approved by Clinical Policy Committee
02/04/2025	Approved by Utilization Management Subcommittee

Outpatient Habilitative Speech Therapy

Fulcrum Clinical Guidelines **Outpatient Habilitative Speech Therapy**	**Original Date: November 2015 (NIA)**
Physical Medicine – Clinical Decision Making	**Last Revised Date: January 2025**
Guideline Number: CLINUM121	**Implementation Date: February 2025**

Policy Statement

Habilitative speech therapy services may or may not be covered by all clients of this organization. If the service is covered, it may or may not require prior authorization. These guidelines apply to all markets and populations, including teletherapy, contracted with this organization through the corresponding state health plans unless a market-specific health plan has been developed. These services must be provided by a skilled and licensed therapy practitioner and in a manner that is in accordance with accepted standards of practice for discipline-specific therapies. It must also be clinically appropriate in amount, duration, and scope to achieve their purpose and considered effective treatment for the current injury, illness, or condition.

Habilitative/Rehabilitative speech therapy should meet the definitions below, be provided in a clinic, an office, at home, or in an outpatient setting and be ordered by either a primary care practitioner or specialist.

Scope

Physical medicine practitioners, including speech language pathologists and speech therapist assistants.

Definitions

Habilitative Speech Therapy: Treatment provided by a state-regulated speech therapist to help a person attain, maintain, or prevent deterioration of a skill or function never learned or acquired. There must be measurable improvement and progress towards functional goals within an anticipated timeframe toward a patient's maximum potential. Treatment may also be appropriate in a child with a progressive disorder when it has the potential to prevent the loss of a functional skill or enhance the adaptation to such functional loss. The condition must be such that there is a reasonable expectation that the services will bring about a significant improvement within a reasonable time frame, regardless of whether the individual has a coexisting disorder. Ongoing treatment is not appropriate when functioning is steady, and treatment no longer yields measurable functional progress.

Rehabilitative Speech Therapy: Treatment provided by a state-regulated speech therapist designed to help a person recover from an acute injury or exacerbation of a chronic condition that has resulted in a decline in functional performance. The specific impact of injury or exacerbation on the patient's ability to perform in their everyday environment must be supported by appropriate tests and measures in addition to clinical observations. Services must be provided within a reasonable time frame (frequency/duration) to restore lost function or to teach compensatory techniques if full recovery of function is not possible.

Functional Skills are considered necessary communication activities of daily life. The initial plan of care documents baseline impairments as they relate to functional communication with specific goals developed that are measurable, sustainable and time specific. Subsequent plans of care document progress toward attainment of these goals in perspective to the patients' potential ability. Discontinuation of therapy will be expected when the maximum therapeutic value of a treatment plan has been achieved, no additional functional improvement is apparent or expected to occur, and the provision of services for a condition cease to be of therapeutic value.

Fulcrum will review all requests resulting in adverse determinations for Medicaid members for coverage under federal Early and Periodic Screening, Diagnostic and Treatment (EPSDT) guidelines.[1,2]

Procedure

1. Must have written referral from primary care practitioner or other non-physician practitioner (NPP) as permitted by state guidelines.
2. When skilled services are also being provided by other community service agencies and/or school systems, the notes must show how the requested services are working in coordination with these agencies and not duplicating services. The extent or lack of these additional services must be indicated in the documentation.
3. Formal testing must be age-appropriate, norm-referenced, standardized, and specific to the therapy provided. Test scores should meet the following criteria to establish presence of a functional delay. Notes should document the following to establish the presence of delays or deficits:
   a) The following methods are generally accepted measures that may be considered to support a significant delay:
      i) Standardized scores at or below the 10th percentile in at least one subtest area for the patient's age.[3]
      ii) Standardized scores greater than or equal to 1.5 standard deviations below the mean in at least one subtest area for the patient's age.[1-8]
      iii) Functional delays may be established by 25% or greater deficit in age equivalency as indicated by established general guidelines of functional assessments or specific criterion-referenced tests or profiles.[1-6]
4. While standardized testing is preferred, scores alone may not be used as the sole criteria for determining a patient's medical need for skilled intervention. Test information must be linked to difficulty with or inability to perform everyday tasks.
5. In the absence of standardized testing or when test scores show skills within normal ranges despite functional deficits, the documentation must include detailed clinical observations and objective data to document the degree and severity of the condition, in order to support the medical need for skilled services. A caregiver interview/questionnaire can also support the request.
6. Any time standardized testing cannot be completed, the documentation must clearly state the reason formal testing could not be done.
7. Treatment goals must be realistic, measurable, and promote attainment of developmental milestones and functional communication abilities appropriate to the patient's age and circumstances. They should include the type, amount, duration, and frequency of therapy services.[9] The amount, frequency, and duration of the services must be consistent with accepted standards of practice. Treatment goals must be individualized and measurable in order to identify the functional levels related to appropriate maintenance or maximum therapeutic benefit. Goals of intervention should target the functional deficits identified by the skilled therapist during the assessment and promote attainment of:
   a) Age-appropriate developmental milestones, functional skills appropriate to the patient's age and circumstances. Although identified as component parts of participation, underlying factors, performance skills, client factors or the environment should not be the targeted outcome of long-term goals. For sustained positive benefits from therapeutic interventions, activities can be practiced in the child's environment and reinforced by the parents or other caregivers. Practice in one's natural environment is essential for success.[10]
   b) The plan of care must include goals detailing type, amount, duration, and frequency of therapy services required to achieve targeted outcomes. The frequency and duration must also be commensurate with the patient's level of disability, medical and skilled therapy needs, as well as accepted standards of practice while reflecting clinical reasoning and current evidence.[9]
8. Frequency and duration of skilled services must also be in accordance with the following:
   a) Intense frequencies (3x/week or more) will require additional documentation and testing supporting a medical need to achieve an identified new skill or recover function with specific, achievable goals within

the requested intensive period[9] Details on why a higher frequency is more beneficial than a moderate or low frequency must be included. Higher frequencies may be considered when delays are classified as severe as indicated by corresponding testing guidelines used in the evaluation. More intensive frequencies may be necessary in the acute phase, however, progressive decline in frequency is expected within a reasonable time frame.

b) Moderate frequency (2x/week) should be consistent with moderate delays as established in the general guidelines of formal assessments used in the evaluation. This frequency may be used for ongoing care when documentation supports this frequency as being clinically effective toward achieving the functional goals in the treatment plan within a reasonable time frame.
c) Low frequency (1x/week or less) may be considered when testing guidelines indicate mild delays or when a higher frequency has not been clinically effective, and a similar outcome is likely with less treatment per week.
d) All requested frequencies must be supported by skilled treatment interventions regardless of level of severity of delay.
e) Additional factors may be considered on a case-by-case basis.

9. There must be evidence as to whether the services are considered reasonable, effective, and of such a complex nature that they require the technical knowledge and clinical decision-making skill of a therapist or whether they can be safely and effectively carried out by non-skilled personnel without the supervision of qualified professionals.
   a) Treatment that requires technical knowledge and clinical decision-making expertise to meet the skilled service needs of the individual. This includes analyzing medical/behavioral data and selecting appropriate evaluation tools/protocols to determine communication/swallowing diagnosis and prognosis.
   b) Progress notes/updated plans of care that cover the patient's specific progress towards their goals with review by the primary care practitioner or other NPP will be required every 60-90 days or per state guidelines. Documentation should include:
      i) The patient's current level of function, any conditions that are impacting his/her ability to benefit from skilled intervention.
      ii) Objective measures of the patient's overall functional progress relative to each treatment goal as well as a comparison to the previous progress report.
      iii) Skilled treatment techniques that are being utilized in therapy as well as the patient's response to therapy and why there may be a lack thereof. Treatment goals that follow a hierarchy of complexity to achieve the target skills for a functional goal.
      iv) Re-evaluation/annual testing (for habilitative therapy) using formal standardized assessment tools and formal assessment of progress must be performed to support progress, ongoing delays and medical necessity for continued services.
      v) An explanation of any significant changes in the plan of care and clinical rationale for why the ongoing skills of a SLP are medically necessary.
   c) If the patient is not progressing, then documentation of a revised treatment plan is necessary. Discontinuation of therapy will be expected when the maximum therapeutic value of a treatment plan has been achieved, no additional functional improvement is apparent or expected to occur, and the provision of services for a condition cease to be of therapeutic value.
   d) It is expected that a specific discharge plan, with the expected treatment frequency and duration, must be included in the plan of care. The discharge plan must indicate the plan to wean services once the patient has attained their goals, if no measurable functional improvement has been demonstrated, or if the program can be carried out by caregivers or other non-skilled personnel.
   e) It is expected that there be evidence of the development of age-appropriate home regimen to facilitate carry-over of target skills and strategies and education of patient, family, and caregiver in home practice exercises, self-monitoring as well as indication of compliance for maximum benefit of therapy.

f) For patients no longer showing functional improvement, a weaning process of one to two months should occur. Behaviors that interfere with the ability to progress with therapy qualify under the ASHA discharge criteria guidelines.[11] If the patient shows signs of regression in function, the need for skilled speech therapy can be re- evaluated at that time. Periodic episodes of care may be needed over a lifetime to address specific needs or changes in condition resulting in functional decline.

g) A maintenance level of therapy services may be considered when a member requires skilled therapy for ongoing periodic assessments and consultations and the member meets one of the following criteria:
   i) Documentation shows the member and the responsible adult have a continuing need for education, or a periodic adjustment of the home program is needed to meet the member's needs.
   ii) Goals in the plan of care must be updated to reflect that care is focused on maintaining the current level of functioning and preventing regression, rather than progressing or improving function.
   iii) Clear documentation of the skilled interventions rendered and objective details of how these interventions are preventing deterioration or making the condition more tolerable must be provided. The notes must also clearly demonstrate that the specialized judgment, knowledge, and skills of a qualified therapist (as opposed to a non-skilled individual) are required for the safe and effective performance of services in a maintenance program.

h) For patients whose language background differs from the rendering therapist and in situations in which a clinician who has native or near-native proficiency in the target language is not available, use of an interpreter is appropriate and should be documented accordingly. If an interpreter is not present, rationale for this should be documented as well as documentation that provides evidence of a communication disorder, and a treatment plan that supports linguistically appropriate services without the use of an interpreter. Further, if a patient is substantially exposed to more than one language, the assessment must evaluate both languages and contain appropriate tests and measures to clearly denote the presence that a communication disorder is present as opposed to normal linguistic variations related to second language learning.[12,13]

i) Swallowing disorders (dysphagia) and feeding disorders will need documentation of an oral, pharyngeal, and/or esophageal phase disorder, food intolerance or aversion. There must be evidence of ongoing progress and a consistent home regimen to facilitate carry-over of target feeding skills, strategies and education of patient, family, and caregiver. Therapies for picky eaters who can eat and swallow normally meeting growth and developmental milestones, eat at least one food from all major food groups (protein, grains, fruits, etc.) and more than 20 different foods is not medically necessary.

j) Documentation should include any applicable coordination of services with other community service agencies and/or school systems. If services are not available, then this should be indicated in the documentation.

10. Treatment that includes goals for reading/literacy must also have a primary diagnosis of a speech or language disorder. Documentation must support that the deficits in reading/literacy are affecting functional activities of daily living and are not the primary focus of treatment. They must show how the services for reading/literacy are of such a complex nature that they require the skills of a speech language pathologist.

Regulatory, Accreditation and Resources

Fulcrum Provider Portal: https://fulcrumproviderportal.com

Medicare NCD & LCD

Article - Billing and Coding: Outpatient Physical and Occupational Therapy Services (A56566) (cms.gov)

NCCI for Medicare | CMS

Article - Billing and Coding: Home Health Speech-Language Pathology (A53052) (cms.gov)

Article - Billing and Coding: Speech Language Pathology (SLP) Services: Communication Disorders (A54111) (cms.gov)

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Policy History

Date	Update
November 2023	New Policy
12/07/2023	Approved by Clinical Policy Committee
12/19/2023	Approved by UM Subcommittee
03/07/2024	Approved by Clinical Policy Committee
03/15/2024	Approved by Utilization Management Subcommittee
01/23/2025	Approved by Clinical Policy Committee
02/04/2025	Approved by Utilization Management Subcommittee

Record Keeping and Documentation Standards: Physical Medicine

Fulcrum Clinical Guidelines **Record Keeping and Documentation Standards: Physical Medicine**	**Original Date: (NIA) November 2015**
Physical Medicine – Clinical Decision Making	**Last Revised Date: January 2025**
Guideline Number: CLINUM122	**Implementation Date: February 2025**

Policy Statement

Recordkeeping is used to document the condition and care of the patient, avoid or defend against a malpractice claim, and support the concurrent and/or retrospective medical necessity requiring the provision of skilled services. The provider is responsible for documenting the evidence to clearly support the foregoing indices and submitting the documentation for review in a timely manner.

These guidelines apply to all markets and populations, including teletherapy, contracted with this organization through the corresponding state health plans unless a market-specific health plan has been developed. To be covered, documentation must contain evidence to support medical necessity and the need for skilled services as appropriated by the following descriptions and definitions.

Definitions

Medical Necessity: Reasonable or necessary services that require the specific training, skills, and knowledge of a physical or occupational therapist and/or speech/language pathologist in order to diagnose, correct, or significantly improve/optimize as well as prevent deterioration or development of additional physical and mental health conditions. These services require a complexity of care that can only be safely and effectively performed by or under the general supervision of a skilled licensed professional.

a) Services shall not be considered reasonable and medically necessary if they can be omitted without adversely affecting the member's condition or the quality of medical care.
b) A service is also not considered a skilled service merely because it is furnished by a skilled licensed professional or by an assistant under the direct or general supervision, as applicable, of that professional. If a service can be self-administered or safely and effectively carried out by an unskilled person, without the direct supervision of a trained professional, as applicable, then the service cannot be regarded as a skilled service even though a licensed professional rendered the service.
c) Similarly, the unavailability of a competent person to provide a non-skilled service, notwithstanding the importance of the service to the patient, does not make it a skilled service when a skilled licensed professional renders the service.
d) Services that include repetitive activities (exercises, skill drills) which do not require a licensed/registered professional's expertise (knowledge, clinical judgment, and decision- making abilities) and can be learned and performed by the patient or caregiver are not deemed medically necessary.
e) Activities for general fitness and flexibility, sports-specific training enhancement or general tutoring for improvement in educational performance are not considered medically necessary.

All network practitioners will maintain clinical documentation that clearly supports the medical necessity of all health care services. In addition, all network practitioners are required to provide additional clinical documentation and/or explanation regarding medical necessity of services at the request of this organization.

Medically necessary care includes the following elements:

a) **Contractual** – all covered medically necessary health care services are determined by the practitioner's contract with the payer and individual health plan benefits.
b) **Scope of Practice** – medically necessary health care services are limited to the scope of practice under all applicable state and national health care boards.
c) **Standard of Practice** – all health care services must be within the practitioner's generally accepted standard of practice and based on creditable, peer-reviewed, published medical literature recognized by the practitioner's relevant medical community.
d) **Patient Safety** – all health care services must be delivered in the safest possible manner.
e) **Medical Service** – all health care services must be medical, not social, or convenient, for the purpose of evaluating, diagnosing, and treating an illness, injury, or disease and its related symptoms and functional deficit. These services must be appropriate and effective regarding type, frequency, level, duration, extent, and location of the enrollee's diagnosis or condition.
f) **Setting** – all health care services must be delivered in the least intensive setting.
g) **Cost** – the practitioner must deliver all health care services in the most cost-effective manner as determined by this organization, the health plan, and/or employer. No service should be more costly than an alternative diagnostic method or treatment that is at least as likely to provide the same diagnostic or treatment outcome.
h) **Clinical Guidelines**– health care services are considered medically necessary if they meet all of the Clinical Guidelines of this organization.

Procedure:

1. General Guidelines:
   a) Documentation should clearly reflect why the skills of a practitioner are needed. The service is considered a *skilled service* if the inherent complexity of the service is such that it can be performed safely and/or effectively only by or under the supervision of a licensed therapist. The deciding factors are always whether the services are considered reasonable, effective treatments requiring the skills of a therapist or whether they can be safely and effectively carried out by non-skilled personnel without the supervision of qualified professionals.
   b) All records (both digital and handwritten) must be legible, which is defined as the ability of at least two people to read and understand the documents.
   c) Documentation should be complete and include the practitioner's signature and credentials, appropriately dated chart entries, and include patient identifications on each page. Any corrections to the patient's record must be made legibly in permanent ink (single line through the error), dated, and authenticated by the person making the correction(s). Electronic documentation should include the appropriate mechanism indicating that a change was made without the deletion of the original record.
   d) Services must be documented in accordance with Current Procedural Terminology (CPT®) coding criteria (e.g., location (body region), time component, etc.).
   e) Adverse events associated with treatment should be recorded in the patient chart.
2. Clinical Documentation
   a) Initial evaluations and re-evaluations including plan of care should document the medical need for a course of treatment through objective findings and subjective self or caregiver reporting. The evaluation must be performed by a licensed PT, OT, ST, MD, DO, or DPM in the state. Pertinent history and general demographics, including past or current treatment for the same condition and a baseline evaluation including current and prior functional status should be submitted for review. Copy of discharge summary, written letter from the member stating when services ended and/or

specific reference to the date the member choosing to end care with a prior provider must be provided if patient has a current authorization with a different provider and is seeking services with a new provider. Treatment should not duplicate services provided in multiple settings or disciplines.

b) Documentation of the evaluations should list and describe the impact of the conditions and complexities on the prognosis and/or the plan for treatment such that it is clear to the peer reviewer that the planned services are reasonable and appropriate for the individual.
c) Objective measures and/or discipline-specific standardized testing demonstrating delays that are connected to a decline in functional status must be provided. (Note: Treatment must not be focused on returning to activities beyond normal daily living, including but not limited to return to sports or work specific tasks). For patients with developmental delay, see Outpatient Habilitative Physical and Occupational Therapy and/or Habilitative/Rehabilitative Speech Therapy Guidelines. Assessment tools used during the evaluation should be valid, reliable, relevant, and supported by the appropriate national therapy best practices guidelines.
d) While outcome assessment measures are preferred, scores alone may not be used as the sole criteria for determining a patient's medical need for skilled intervention. Test information must be linked to difficulty with or inability to perform everyday tasks.[1]
e) In the absence of objective measures, the report must include detailed clinical observations of current skill sets, patient or caregiver interview/questionnaire and/or informal assessment supporting functional mobility/ADL deficits and the medical need for skilled services. The documentation must clearly state the reason formal testing could not be completed.
f) Functional outcome assessment and/or standardized test results with raw scores, standardized scores, and score interpretation must be included.
g) Detailed clinical observations, as well as prognosis and rehab potential, must be outlined.
h) Contraindications to care must be listed with an explanation of their current management.
i) School programs, including frequency and goals to ensure there is no duplication (for Habilitative OT/PT/ST).
j) Information regarding child's involvement in home and community programs (for Habilitative OT/PT/ST).
k) Daily notes should include clear evidence of skilled treatment interventions that cannot be carried out solely by non-skilled personnel, assessment of patient's response or non- response to intervention and plan for subsequent treatment sessions, assessments, or updates, and any significant, unusual, or unexpected changes in clinical status.

3. Treatment plan or Plan of Care should include the following:
   a) Meaningful clinical observations; the patient's response to the evaluation process; and interpretation of the evaluation results, including prognosis for improvement and recommendations for therapy amount, frequency, and duration of services.
   b) The plan of care must include measurable short- and long-term functional SMART (specific, measurable, attainable, realistic and time-bound[3,4]) goals detailing type, amount, duration, and frequency of therapy services required to achieve targeted outcomes, linked to functional limitations outlined in the most recent evaluation/assessment. The frequency and duration must also be commensurate with the patient's level of disability, medical and skilled therapy needs as well as accepted standards of practice while reflecting clinical reasoning and current evidence.[2]
   c) Visits or units requested must not exceed the frequency and duration supported in the plan of care.
   d) Frequency and duration of skilled services must also be in accordance with the following:
      i) Intense frequencies (3x/week or more) will require additional documentation and testing supporting a medical need to achieve an identified new skill or recover function with specific, achievable goals within the requested intensive period.[2] Details on why a higher frequency is

more beneficial than a moderate or low frequency must be included. Higher frequencies may be considered when delays are classified as severe as indicated by corresponding objective measures and/or testing guidelines used in the evaluation. More intensive frequencies may be necessary in the acute phase; however, progressive decline in frequency is expected within a reasonable time frame.

ii) Moderate frequency (2x/week) should be consistent with moderate delays as established by objective measures and/or the general guidelines of formal assessments used in the evaluation. This frequency may be used for ongoing care when documentation supports this frequency as being clinically effective toward achieving the functional goals in the treatment plan within a reasonable time frame.

iii) Low frequency (1x/week or every other week) may be considered when objective measures and/or testing guidelines indicate mild delays or when a higher frequency has not been clinically effective, and a similar outcome is likely with less treatment per week.

iv) Additional factors may be considered on a case-by-case basis.

v) Requested frequency/duration must be supported by skilled treatment interventions regardless of level of severity of deficit or delay.

e) Intervention selections must be evidence-based, chosen to address the targeted goals and representative of the best practices outlined by the corresponding national organizations.[5,6] Treatment plan should include the type of modalities and treatment interventions to be provided, any expected caregiver involvement in the patient's treatment, educational plan, including home exercises, ADL modifications, and anticipated discharge recommendations, including education of the member in a home program and, when applicable, primary caregiver education.

f) Plan of care should be reviewed at intervals appropriate to the patient and in accordance with state and third-party requirements. This review should include total visits from the start of care, changes in objective outcome measures, overall progress towards each goal (including where goal has been met or not met), and any modification of treatment interventions in order to meet goals. Goals should be updated and modified as appropriate. The plan of care update should outline a summary of a patient's response (or lack thereof) to intervention and a brief statement of the prognosis or potential for improvement in functional status, and any update to the frequency or amount of expected care, in preparation for discharge.

g) The plan of care should clearly support why the skills of a professional are needed as opposed to discharge to self-management or non-skilled personnel without the supervision of qualified professionals. If telehealth is included, the plan of care should clearly support why the skills of a professional are needed as opposed to discharge to self-management or non-skilled personnel without the supervision of qualified professionals.

h) Anticipated discharge planning should be included in plans of care. Formal discharge from care should be considered when records demonstrate services are unskilled or could be completed as part of a home management program, functional limitations do not support the rate of care requested (stated above) or treatment is provided without a treatment plan, functional goals, or recent, sustained improvement.

4. Reviewers determine that claims/requests have insufficient documentation when the medical documentation submitted is inadequate to support a request for services as medically necessary or requiring skilled services for the requested amount of care. Incomplete notes (e.g., unsigned; undated; insufficient detail, such as lacking updated objectives, updated goals, or specific plan of care) may also result in a denial for lack of sufficient information.
5. All contracted practitioners will treat patient identifiable health information according to HIPAA standards to ensure the confidentiality of the record and provide the minimum necessary information when requested to perform a review of services.

Regulatory, Accreditation and Resources

Fulcrum Provider Portal: https://fulcrumproviderportal.com
Medicare NCD & LCD
NCCI for Medicare | CMS

Clinical Resources

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Policy History

Date	Update
November 2023	New Policy
12/07/2023	Approved by Clinical Policy Committee
12/19/2023	Approved by UM Subcommittee
03/07/2024	Approved by Clinical Policy Committee
03/15/2024	Approved by Utilization Management Subcommittee
01/23/2025	Approved by Clinical Policy Committee
02/04/2025	Approved by Utilization Management Subcommittee

Active Care Procedures

Fulcrum Clinical Guidelines **Active Care Procedures**	**Original Date: June 2018 (NIA)** **January 2018 (Fulcrum)**
Physical Medicine – Clinical Decision Making	**Last Revised Date: January 2025**
Guideline Number: CLINUM 103	**Implementation Date: February 2025**

Policy Statement

Active care services have sufficient evidence to support superior outcomes when used alone or in combination with manual-based treatments and/or passive care services.[1,2] This policy will apply to all physical medicine participating network practitioners who provide active procedures, data/claims processing, and peer reviewers. Physical medicine practitioners include chiropractors, physical therapists, occupational therapists, and speech language pathologists.

Purpose

These guidelines will assist the evidence-based physical medicine provider to properly choose the correct service(s) when indicated for proper overall case management.

Definitions

The following services are considered "active" meaning the patients themselves take part in the completion of the service. This is opposed to "passive", where the patient passively receives health care services without any physical input or effort.

All services outlined in this section require the provision of skilled services and direct (one-on- one) provider-patient contact. While an individual's medical condition is a valid factor in making decisions about health care, the diagnosis or prognosis cannot be the sole basis in deciding that skilled care services are reasonable and necessary. The key judgment is whether the skills of a qualified health care provider are needed to treat the illness or injury or whether the services can be carried out by unskilled personnel.

Regardless of the expectation of improvement, reasonable and necessary skilled care services must be provided by a qualified health care provider and require a high level of complexity and sophistication, or the condition of the patient is such that the services can be safely and effectively performed only by a qualified health care provider. Services that do not require the performance or supervision of a qualified health care provider are not skilled and are not considered reasonable or necessary services, even if they are performed or supervised by a qualified professional. Therefore, if a service can be self-administered or safely and effectively furnished by an unskilled person or caregiver, without the direct or general supervision of a qualified health care provider, the service cannot be regarded as skilled even if a qualified professional actually furnishes the service. Further, the unavailability of a competent person to provide a non-skilled service, despite the importance of the service to the patient, does not make it a skilled service when a qualified health care provider furnishes the service. A clinician may not merely supervise but must apply the skills of a professional by actively participating in the treatment of the patient. In addition, a provider's skills may be documented, for example, by the clinician's descriptions of their skilled treatment, the changes made to the treatment due to a clinician's assessment of the patient's needs on a particular treatment day or changes due to progress the clinician judged sufficient to modify the treatment toward the next more complex or difficult task.

Services related to activities for the general good and welfare of patients (e.g., general exercises to promote overall fitness and flexibility and activities to provide diversion or general motivation) do not constitute skilled care services. Services provided by practitioners/staff who are not qualified health care providers are not skilled

intervention services. Unskilled services are palliative procedures that are repetitive or reinforce previously learned skills or services performed to maintain function.

Objective Evidence: Consists of serial standardized assessment tools/instruments, outcome measurements, and or measurable assessments of functional outcome used to quantify patient progress and support justification for continued treatment. Examples of objective evidence include:

a) Functional assessment from standardized and validated outcomes instruments; or
b) Functional assessment scores from tests and measurements that are validated in the professional literature, which are appropriate for the condition/function being measured.

Physical measures (e.g., range of motion or manual muscle strength testing) are generally not considered to be 'objective evidence' of functional assessment.

Rehabilitative (Restorative) Services: Services designed to address recovery or improvement in function and, when possible, restoration to a previous level of health and well-being. Improvement is evidenced by successive objective measurements whenever possible (e.g., impairments, pain, functional status, etc.). If an individual's expected rehabilitation potential is insignificant in relation to the extent and duration of therapy services required to achieve such potential, rehabilitative therapy is not reasonable and necessary. Rehabilitative care must require the skills and level of sophistication of a qualified health care provider. Services that can be safely and effectively furnished by non-skilled personnel or caregivers are not rehabilitative care services.

Skilled rehabilitative care services must be part of a documented treatment plan provided to improve or restore lost or impaired physical function resulting from illness, injury, neurologic disorder, congenital defect, or surgery. These skilled care services are intended to enhance rehabilitation and recovery by clarifying a patient's impairments and functional limitations as well as by identifying interventions, treatment goals, and precautions.

Reasonable and Necessary: The services shall be of such a level of complexity and sophistication, or the condition of the patient shall be such that the services required can only be performed safely and effectively by a qualified health care provider. Services that do not require the performance of a qualified health care provider are not skilled and are not considered reasonable or necessary.

Procedure

1. Clinical Reasoning:
   The current valid literature indicates the necessity of incorporating active care measures into treatment programs. Interventions chosen to treat the patient's symptoms or conditions should be selected based on the most effective and efficient means of achieving the patient's functional goals.[3]
2. Timing of Introduction
   a) **Acute care cases**- The literature supports the introduction and management of active care procedures as soon as clinically possible once the patient has sufficient range of motion/functional ability. For the care to be considered beneficial and effective, active care services should generally be provided within the first two weeks of intervention. For the purpose of these guidelines, an acute care case is when a patient is seen for treatment within seven days of the onset of the illness, injury, and/or medical intervention.[4]
   b) **Subacute care cases**- Similar to acute care cases, the literature supports the introduction and management of active care procedures as soon as clinically possible once the patient has sufficient range of motion/functional ability. For the care to be considered beneficial and effective, active care services should generally be provided within the first two weeks of intervention. For the purpose of these guidelines, a subacute care case is when a patient is seen for treatment between

7 and 21 days after the onset of an illness, injury, and/or medical intervention.

c) **Chronic care cases**- The literature supports the introduction and management of active care procedures at the onset of intervention, either the first or second visit. For the purpose of these guidelines, a chronic care case is when a patient is seen for treatment beyond 21 days after the onset of an illness, injury, and/or medical intervention. Chronic conditions that have intermittent episodes will also be considered chronic in nature for the purpose of these guidelines.[4]

3. **Documentation Requirements**
   a) Documentation must support the medical necessity for the services requested and why the skills of a licensed professional are needed to render the service. The provider must outline the patient-specific rationale/need for care and intervention as it relates to the patient's condition and resultant functional limitations in activities of daily living, as well as mobility and safety, as identified in a comprehensive evaluation. Based on these findings, a plan of care is developed that includes specific and measurable goals that support the need for the identified interventions.[5]
   b) Documentation must include a timeframe for initiating, progressing, and discharging the patient from skilled services. Documentation must also include specific treatment parameters to support the intervention, in addition to applicable precautions. This includes the specific type of procedure, instruction and/or exercise performed, area of body and muscle groups treated, and time component.[5]
4. **Billing Units**
   a) Fulcrum follows Medicare rules for reporting timed units.[6] Billing units are based on 15 minutes per unit for time-based codes and the Medicare minimum time requirement for a service to be justifiably billed.

1 unit	≥ 8 minutes to 22 minutes
2 units	≥ 23 minutes to 37 minutes
3 units	≥ 38 minutes to 52 minutes
4 units	≥ 53 minutes to 67 minutes
5 units	≥ 68 minutes to 82 minutes
6 units	≥ 83 minutes to 97 minutes
7 units	≥ 98 minutes to 112 minutes
8 units	≥ 113 minutes to 127 minutes

   b) Individual states may have varying statutory guidelines for reporting timed units that supersede this organization's requirements.

CPT Code Definitions, Examples and Requirements

1. **97110 - Therapeutic Exercise**
   i) Definition: Although not exclusive by definition, therapeutic exercise is any exercise planned and performed to attain a specific goal. Goals would be to increase strength, endurance, range of motion, and flexibility. Therapeutic procedures/exercise could be applied to one or more areas and billed in units as noted above.
   ii) Parameters for Use: The following requirements must be documented in the medical record to support and justify the use of all therapeutic procedures/exercises:
      i) Evidence to support medical necessity
      ii) Plan of care with specific and measurable goals and timeframe for initiating, progressing, and discharging the patient from skilled medical services to an independent home program
      iii) Detailed description of active care services including:
         (1) What exercise(s) were provided
         (2) What area and muscle groups the exercise(s) were provided to
         (3) Amount and type of resistance, number of repetitions and sets, and time component

iv) Evidence to support the need for skilled services completed by a licensed professional in direct contact with one patient

iii) Medical research supports the initiation of appropriate therapeutic procedures/exercise as soon as the patient is reasonably able to engage in the planned activity. Therefore, the expectation is for a patient to perform therapeutic exercises and receive a home exercise program within a reasonable timeframe.[7-18] Based on the definition and guidelines for services that are medically necessary, the expectation is for the provision of the therapeutic procedures/exercises that are not for the convenience of the patient or health care provider or more costly than an alternative form of treatment

iv) Guidelines regarding the use of fitness machines (MedX equipment, cervical/lumbar extension machines, Isostation B-220 Lumbar Dynamometer, Cybex Back System, etc.) show insufficient evidence that they are more efficacious than standard exercise equipment or that their use improves clinical outcomes to a greater extent than standard programs.

v) Documentation must:
   i) Clearly state why the intervention is medically necessary. Provide evidence to support number of visits that are often in excess of community standards for treatment of musculoskeletal conditions
   ii) Provide evidence of functional improvement as a result of the increased muscle strength
   iii) Clearly state the skilled service being provided
   iv) Provide evidence for why the skills of a physical medicine provider/practitioner are needed beyond progressing weights and repetitions
   v) Provide evidence for why the skills of a physical medicine provider/practitioner are needed beyond a few visits to establish a program
   vi) Show that the therapeutic exercise is part of a comprehensive rehab program
   vii) Include a plan of care driven by impairments, not the intervention itself
   viii) Clearly demonstrate that increasing muscle strength is the treatment of choice (e.g., strength building may be detrimental in an individual with movement restrictions).

vi) Examples

Strengthening of select muscle groups (beginning in gravity-eliminated plane, if needed) progressing to anti-gravity plane utilizing body weight with progressive resistive exercises utilizing thera-tubing, exercise ball, free weights, etc.; closed chain exercises are often preferable to open chain exercises in preventing shearing forces and simulating functional activities); monitored graded exercise following cardiac or pulmonary surgery or heart attack; selective stretching to increase joint range of motion (ROM).

vii) Support for this service
   i) Indications must be documented for loss or restriction of joint motion, reduced strength, and functional capacity or mobility concerns. The clinical records must show objective (quantitative if possible) loss of ROM, strength, flexibility, or mobility. The code is generally not reimbursable for increasing a patient's endurance without deficits, promotion of overall fitness, weight loss, return to work, return to sports, for sport(s) and/or recreation, and/or sports and aerobic conditioning.
   ii) Documentation must include evidence of the skilled services required to support the use of therapeutic exercise. It is considered a skilled service that would require proper licensure/credentials of the clinician. Without evidence in the documentation to support the need for skilled services, the records would suggest the patient is "working out" in the clinical setting, which is generally not medically necessary and not eligible for reimbursement.

iii) Most programs should entail one to three units at any time to ensure competency and compliance with instructions. The clinical rationale for more than three units would need to be clearly supported by documentation. If more than three units are being utilized per session, this might indicate the patient is "working out" in the clinical setting which is generally not considered medically necessary.

iv) Patient non-compliance with active home instructions will not result in further in-office instruction being considered medically necessary. The patient should instead be discharged for non-compliance/acting against medical advice.

v) One to three sessions of in-office exercise should be sufficient, for the non-surgical patient, to ensure competency and compliance with a home exercise program. If in- office repetitive exercise continues after 3 sessions, the record must clearly document why the patient is not able to participate in a home exercise program. Any active care program may include periodic review of the program as part of case management in regard to monitoring continued therapeutic benefit and progression in specific exercises/instructions. This ongoing case management should outline patient compliance, necessary alterations to any active home care program, progression in specific active home care program, and anticipated term date for the need for skilled in- office services.

2. **97112 - Neuromuscular re-education**[19]

a) Definition: Neuromuscular re-education of movement, balance, coordination, kinesthetic sense, posture, and proprioception (defined as the three modalities of joint position: sense, sense of movement and sense of force). Injuries can be seen after stroke, closed head injury, spinal cord injury, tumor, congenital disorders such as cerebral palsy or secondary to degenerative joint disease, musculoskeletal injury such as ankle sprain, post orthopedic surgery, or prolonged immobilization. Neuromuscular re-education may be considered medically necessary if at least one of the following conditions is present and documented:

i) The patient has the loss of deep tendon reflexes and vibration sense accompanied by paresthesia, burning, or diffuse pain of the feet, lower legs, and/or fingers.

ii) The patient has nerve palsy, such as peroneal nerve injury causing foot drop.

iii) The patient has muscular weakness or flaccidity, as a result of a cerebral dysfunction, a nerve injury or disease, or has had a spinal cord disease or trauma.

iv) The patient has muscle compensations requiring targeted exercise to produce stable, coordinated movements during functional tasks.[20]

v) The patient has peripheral or central vestibular dysfunction causing dizziness, vertigo, imbalance, or disequilibrium that supports the use of Vestibular Balance and Rehabilitation Therapy (VBRT).[21,22]

b) Examples

Treatment involves the stimulation of reflexes, sensation, posture, proprioception and motor activity through rocker/BAPS board, mini-trampolines, targeted exercises to spastic or rigid muscles, balance training, proprioceptive neuromuscular facilitation (PNF), Feldenkrais, Bobath, neurodevelopmental treatment (NDT), and desensitization techniques.

c) Support for this service

i) Documentation must support the need for skilled services by a licensed professional in direct contact with one patient.

ii) An indication of the lesion of the neuromusculoskeletal system needs to be documented and the exact procedure must be noted. Instructions for home care should be seen within a reasonable timeframe and the service discontinued with proper education and instruction given to the patient.

3. **97113 - Aquatic Therapy**[23]

a) Definition: A therapy program utilizing therapeutic exercise techniques with the properties of water, designed and carried out in a suitably heated hydrotherapy pool by a qualified clinician specifically for

an individual to improve function. Examples: Ai Chi, Aquatic PNF,[24] the Bad Ragaz Ring Method,[25,26] Fluid Moves, the Halliwick Concept,[27,28] Swim Stroke Training and Modification, Task Type Training Approach and Watsu.[29] Treatment to address improved circulation and decreased venous pooling, increased endurance facilitated through the availability of cardiovascular training with less stress on weight-bearing joints or working with enhancement of balance and coordination as a result of the buoyancy obtained from an aquatic environment.

b) Support for this Service
   i) Documentation must support the need for skilled services by a licensed professional in direct contact with one patient. The patient would need to be immersed in a pool of water for this code to apply.
   ii) The provider must also indicate the medical necessity for the buoyancy, hydrostatic pressure, and heat properties that are present in a pool setting versus standard land-based therapeutic exercise or activities. This is often used to transition the patient to a land-based program.

4. **97116 - Gait Training**
   a) Definition: Training the patient in specific activities that will facilitate ambulation on varied surfaces and stair climbing with or without an assistive device. This includes training in rhythm, speed, sequencing, and safety instructions.
   b) Examples
   Gait training can be useful for people with any condition needing to re-learn proper ambulation to allow for functional performance and mobility. Common conditions include amputation, osteoarthritis, muscular dystrophy, cerebral palsy, stroke, Parkinson's disease, multiple sclerosis, brain/spinal cord injuries, post-surgical, sports injury, and low back pain.
   c) Support for this Service
      i) The provider should consider the contextual factors that affect a person's ability to participate meaningful ADLs. Gait training and ambulation interventions should directly address functional mobility.[30]
      ii) Documentation must support the need for skilled services by a licensed professional in direct contact with one patient as opposed to just addressing endurance deficits alone, or continue to treat until the patient can move to a lesser supportive assistive device.
      iii) Deficits in gait parameters including walking speed, cadence, stride length and balance, and functional ambulation category scores must be documented. The provider would need to document if body-weight support (BWS) systems, unweighting devices, or assistive devices are used. The record must denote the assessment of the phases of gait to include stance phase, stride length, balance issues and what the ankle, knee, hip, and low back are doing during the phases of gait cycle.

5. **97760 - Orthotics Management and Training**
   a) Definition: Orthotic(s) management and training, including assessment and fitting when not otherwise reported as a separate L HCPCS code (L-code), fitting and training, upper extremity or extremities, lower extremity or extremities, and/or trunk, each 15 minutes.
   b) Explanation:
      i) This code applies to custom-fabricated orthotics and for adjustments to over-the-counter orthotics. The orthotics management portion of this code refers to time spent assessing the need for the orthotic and the type of orthotic as well as the fitting and the fabrication if the fabrication is done in the presence of the patient. The training portion of this code includes training in the care and use of the orthotic device.
      ii) This code cannot be used if the orthotic is fabricated/formed without the patient being present. Supplies and time for the actual orthotic fabrication is typically reported under L-codes. If an L- code is NOT used to report the orthotic, then the time assessing and fitting/fabricating would be reported under code 97760.
   c) Support for this service

i) The need for an orthotic requires documented support. This would include a proper examination (not just a vendor specific evaluation) along with the outline of the causal nexus to justify inclusion for any complaints other than foot-based. Foot-based complaints need a detailed notation as to the fault/deficit present that requires custom orthotics versus usage of a heel lift or over-the- counter orthotic. This service should typically not be seen more than once per calendar year for one set of orthotics. Orthotic use is based on plan benefit.
ii) Documentation must also support why the skills of a licensed professional are needed for the training in care and use of the orthotic.

6. **97761 - Prosthetic Training**
   a) Definition: Functional mobility and activities of daily living (ADL) assessment, training with prosthesis, upper and/or lower extremity. This would include instruction and practice in use of prosthesis.
   b) Support for this service: The patient would need to be the recipient of a prosthetic device or require adjustments to current prosthetic device to improve function.
7. **97763 - Checkout for Orthotic/Prosthetic Use, Established**
   a) Definition: Orthotic(s)/prosthetic(s) management and/or training, upper extremity or extremities, lower extremity or extremities, and/or trunk, subsequent orthotic(s)/prosthetic(s) encounter
   b) Support for this service: Documentation must clearly support the skilled need of a licensed professional for the adjustments.
8. **97530 - Therapeutic Activities**
   a) Definition: This code includes the use of dynamic activities in teaching and training the patient to improve functional performance in a progressive manner.
   b) Examples: Activities that address quantifiable deficits (e.g., loss of ROM, strength, or functional capacity) resulting in a deficit in functional mobility. Functional mobility may include bending, reaching, lifting, carrying, pushing, pulling, bed mobility and transfers.
   c) Support for this service:
      i) Documentation must support the need for skilled services by a licensed professional in direct contact with one patient.
      ii) In order for therapeutic activities to be covered, all the following requirements must be met:
         (1) The patient has a condition for which therapeutic activities can reasonably be expected to restore or improve function.
         (2) The patient's condition is such that he/she is unable to perform therapeutic activities except under the direct supervision of a physician, occupational therapist, or physical therapist.
         (3) There is a clear correlation between the type of exercise performed and the patient's underlying medical condition for which the therapeutic activities were prescribed.
   d) The code is generally not reimbursable for increasing a patient's endurance without deficits, promotion of overall fitness, weight loss, return to sports, and/or sports and aerobic conditioning.
9. **97129 Cognitive Skills Development**
   a) Definition: Therapeutic interventions that focus on cognitive function (e.g., attention, memory, reasoning, executive function, problem solving, and/or pragmatic functioning) and compensatory strategies to manage the performance of an activity (e.g., managing time or schedules, initiating, organizing, and sequencing tasks), direct (one-on-one) patient contact.
   b) Examples: Individuals with inherited learning disabilities, individuals who have lost cognitive skills as a result of illness or brain injury
   c) Support for this Service: Cognitive deficits would need to be present and quantifiably documented. Documentation must support the need for skilled services by a licensed professional in direct contact with one patient.
10. **97533 - Sensory Integration**
    a) Definition: Treatment techniques designed to enhance sensory processing and adaptive responses to

environmental demands. The goal of sensory integration therapy is to improve the way the brain processes and adapts to sensory information as a foundation for later, more complex learning behavior.

b) Examples:
   i) Sensory integration (SI) therapy has been proposed as a treatment of developmental disorders in patients with established dysfunction of sensory processing (e.g., children with autism, attention deficit hyperactivity disorder (ADHD), fetal alcohol syndrome, and neurotransmitter disease). Sensory integration disorders may also be a result of illness or brain injury.
   ii) Therapy usually involves activities that provide vestibular, proprioceptive, tactile, visual, and auditory stimuli, which are selected to match specific sensory processing deficits of the child. For example, swings are commonly used to incorporate vestibular input, while trapeze bars and large foam pillows or mats may be used to stimulate somatosensory pathways of proprioception and deep touch. Tactile reception may be addressed through a variety of activities and surface textures involving light touch.
   iii) This differs from neuromuscular re-education (97112) as neuromuscular re-education focuses on training to restore the ability to perform particular activities versus training to enhance sensory processing and adaptive responses.

c) Support for this Service
   i) Sensory integration therapy is usually provided by occupational and physical therapists who are certified in sensory integration therapy.
   ii) Documentation must support the need for skilled services by a licensed professional in direct contact with one patient.

11. **97535 -Self-care/Home Management Training**
   a) Definition: Instructing and training the patient in self-care and home management activities (ADL). This includes compensatory training, safety procedures, and instruction in the use of assistive technology devices/adaptive equipment.
   b) Examples: Activities that address quantifiable deficits resulting in functional limitations in ADLs, such as toileting, continence, bathing, dressing, personal hygiene, housecleaning, eating and meal preparation.
   c) Support for this service
      i) Documentation must support the need for skilled services by a licensed professional in direct contact with one patient.
      ii) Documentation should relate the ADL instruction to the patient's expected functional goals and indicate that it is part of an active treatment plan directed at a specific goal.
12. **97542 -Wheelchair Management and Training**
   a) Definition: Includes assessment, fitting, and adjustment of the wheelchair and seating; instructing the patient and/or caregiver on how to propel and safely operate the wheelchair (97001 and 97002 cannot be billed with this code).
   b) Support for this service:
      i) Documentation should include the recent event that prompted the need for a skilled wheelchair assessment; the result of any previous wheelchair assessments; most recent prior functional level; the interventions that were tried by nursing staff, caregivers, or the patient to address poor seating or positioning; and any functional deficits or applicable impairments, such as ROM, strength, sitting balance, skin integrity, sensation, and tone.
      ii) The documentation must correlate the training provided to the expected functional goals that are attainable by the patient and/or caregiver, along with the response of the patient to the instruction or fitting.
      iii) The documentation must clearly support that the services rendered required the skills and expertise of a licensed therapist.
13. **97537 -Community Work Reintegration – typically not a covered service**

a) Definition: Services are instructing and training the patient in community and/or work re-integration activities. These activities could include shopping, safely accessing transportation sources, money management, avocational activities and/or work environment/modification analysis,[31] work task analysis, and use of assistive technology devices and/or adaptive equipment.
b) Examples
    i) Community reintegration is often performed in conjunction with other therapeutic procedures such as gait training and self-care/home management training. The payment for community reintegration training is often bundled into the payment for those other services. Therefore, those other services are not usually separately reimbursable.
    ii) Services provided to issue, modify, adjust, and/or educate the patient on assistive technology devices and/or adaptive equipment typically will not be covered if the adaptive equipment and/or assistive technology device(s) are not covered by the third-party payer.
    iii) Generally, services which are related solely to specific employment opportunities, work skills, or work settings are not reasonable and necessary for the diagnosis and treatment of an illness or injury and are excluded from coverage by Section 1862(a)(1) of the Social Security Act.
c) Support for this Service: Documentation would need to provide evidence to support the medical necessity and the need for skilled services provided to the patient.

14. **97545 -Work Hardening/Conditioning – typically not a covered service**– initial 2 hours, use 97546 for each additional hour and use in conjunction with 97545
    a) Definition: Work hardening includes job simulation tasks and educational activities related to a safe return to work for the patient. Often, work hardening programs incorporate an interdisciplinary approach to restore physical, behavioral, and/or vocational functions. Work conditioning includes exercises directed towards safely returning the patient to work-related activities or to commence with vocational rehabilitation services. In general, work conditioning programs are designed to address neuromuscular functions, such as flexibility, strength, endurance, and/or range of motion, as well as cardiopulmonary functions.
    b) Example: A work-induced injury and/or impairment was present that resulted in the need for therapeutic exercises/procedures. Once the patient has completed acute medical care, including chiropractic or rehabilitation treatment, the patient may require a comprehensive, intensive, and individualized program for safely returning to work activities. Subsequently, the patient may begin a work hardening and/or work conditioning program. Typically, the patient will participate in a program for at least two hours a day, three days a week to as much as eight hours a day, five days a week. The activities performed by the patient in the program may include an exercise regimen, simulation of specific or general work requirements, training and/or modifications of activities of daily living, injury prevention training, cognitive-behavioral pain management training, and/or occupational/educational training aspects.
    c) Support for this Service: The documentation would need to support that the patient had an injury and/or impairment within the last 12 months, has received acute rehabilitation services, and is expected to return to his/her previous employment. Furthermore, the documentation should clearly report the patient's limitations for returning to work; the patient's willingness to participate in the program; a highly structured, goal-oriented plan of care, including reference to return to work and discharge from skilled services; identified systemic neuromusculoskeletal deficits that interfere with work; documentation to support that care is at the point of resolution for the initial or principal injury so that participation in the conditioning process would not be prohibited; and, if applicable, the identification of psychosocial and/or vocation problems and evidence of a referral to the appropriate professional.

Regulatory, Accreditation and Resources

Fulcrum Provider Portal: https://fulcrumproviderportal.com

Medicare NCD & LCD

1. Article - Billing and Coding: Outpatient Physical and Occupational Therapy Services (A56566) (cms.gov)
2. Article - Billing and Coding: Outpatient Physical and Occupational Therapy Services (A57067) (cms.gov)
2. NCCI for Medicare | CMS
3. Article - Billing and Coding: Home Health Occupational Therapy (A53057) (cms.gov)
4. Article - Billing and Coding: Home Health Physical Therapy (A53058) (cms.gov)
5. Article - Billing and Coding: Outpatient Occupational Therapy (A53064) (cms.gov)
6. Article - Billing and Coding: Outpatient Physical Therapy (A53065) (cms.gov)
7. Article - Billing and Coding: Physical Therapy - Home Health (A57311) (cms.gov)
8. LCD - Physical Therapy - Home Health (L33942) (cms.gov)

NCQA UM 2 Element A Clinical Criteria for UM Decisions

Clinical Resources

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Policy History

Date	Update
03/08/2017	New Document
02/06/2018	Reviewed by Clinical Policy Committee
2/7/2018	Approved by UM Subcommittee
2/6/2019	Approved by Clinical Policy Committee
2/12/2019	Approved by UM Subcommittee
3/12/2020	Approved by Clinical Policy Committee
3/31/2020	Approved by UM Subcommittee
3/11/2021	Approved by Clinical Policy Committee
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3/17/2022	Approved by Clinical Policy Committee
3/29/2022	Approved by UM Subcommittee
03/21/2023	Approved by Clinical Policy Committee
05/02/2023	Approved by UM Subcommittee
November 2023	Merged NIA and Fulcrum Active Care Procedures into a single policy. Other policies retired.
12/07/2023	pproved by Clinical Policy Committee
12/19/2023	pproved by UM Subcommittee
03/07/2024	Approved by Clinical Policy Committee
03/15/2024	Approved by Utilization Management Subcommittee
01/23/2025	Approved by Clinical Policy Committee
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Durable Medical Equipment

Fulcrum Clinical Guidelines **Durable Medical Equipment**	**Original Date: June 2018 (NIA)** **January 2018 (Fulcrum)**
Physical Medicine – Clinical Decision Making	**Last Revised Date: January 2025**
Guideline Number: CLINUM 110	**Implementation Date: February 2025**

Policy Statement

This policy will be used to define Durable Medical Equipment (DME), explain the medical necessity of the DME or support for prior authorization of DME.

Purpose

The purpose of this policy applies medical necessity criteria to DME requests for adult and pediatric members in any setting and is applicable to all physical medicine practitioners, including chiropractors, physical therapists, occupational therapists, and speech language pathologists.

Definitions

1. DME is any equipment that provides therapeutic benefits to an individual for certain conditions and/or illnesses defined below.
2. DME consist of items which:
   a) Are used to treat a defined illness or injury.
   b) Are useful to a person with an illness or injury.
   c) Are reusable and durable enough for repeated use.
   d) Are appropriate for use outside of a medical setting such as home, at school, or work.
3. DME includes but is not limited to:
   a) Back, knee, and ankle supports/braces
   b) Cervical collars
   c) Foot orthotics
   d) Electrical stimulation units and supplies
   e) Traction devices
   f) Hospital beds
   g) Equipment to aid with bathing, toileting, and dressing
   h) Splints/slings
   i) Equipment to aid with seating and positioning
   j) Wheelchairs and assistive devices for gait
4. The use of any DME must have evidence of efficacy in the peer-reviewed guideline, systematic review, and/or randomized controlled trial medical literature. The use of these devices is not considered medically necessary in the absence of scientific evidence in peer-reviewed medical literature.[1-3]

Procedure

1. Durable Medical Equipment and services are medically necessary when ALL of the following criteria are met:
   a) The equipment is expected to provide improvement in specific measurable functional deficits related to a documented illness or injury.
   b) The DME is provided by a health care professional.
   c) The equipment has significant medical uses.
   d) Lesser or alternative options have been ruled out.
   e) The clinical records clearly establish the medical need for the DME.

2. Clinical documentation must include the following elements:
   a) A diagnosis that justifies the equipment or supply being requested.
   b) A treatment plan (anticipated start and end date) for the training and/or use of the DME
   c) Measurable functional deficit(s)
   d) Expected outcomes and benefit related to a measurable functional deficit.
   e) Explanation of the healthcare providers training/education, supervision, and monitoring of the use of the DME, as evidenced by the identification of provider type and signature in the record.
   f) Evidence of a trial of conservative services that failed to improve a measurable functional deficit unless contraindicated.
   g) When appropriate, evidence of an in-office trial use that provided improvement in a measurable functional deficit.
   h) When appropriate, evidence of home or vehicle assessment to ensure equipment could be utilized in the home or vehicle.
   i) Evidence of prior equipment for a similar purpose, and reasons that equipment no longer meets current needs.
   j) If an insurance plan does not cover the specific DME, then any visit associated with instruction on the DME would not be covered.
   k) For Medicare: validate coverage and requirements by searching MCD Search Results (cms.gov). A limited set of Articles, Local and National Coverage are included below.

Regulatory, Accreditation and Resources

Fulcrum Provider Portal: https://fulcrumproviderportal.com

Medicare NCD & LCD

1. NCD - Durable Medical Equipment Reference List (280.1) (cms.gov)
2. NCCI for Medicare | CMS
3. Article - Billing and Coding: Outpatient Physical and Occupational Therapy Services (A56566) (cms.gov)
4. Article - Billing and Coding: Outpatient Physical and Occupational Therapy Services (A57067) (cms.gov)
5. NCCI for Medicare | CMS
6. Article - Billing and Coding: Home Health Occupational Therapy (A53057) (cms.gov)
7. Article - Billing and Coding: Home Health Physical Therapy (A53058) (cms.gov)
8. Article - Billing and Coding: Outpatient Occupational Therapy (A53064) (cms.gov)
9. Article - Billing and Coding: Outpatient Physical Therapy (A53065) (cms.gov)
10. Article - Billing and Coding: Physical Therapy - Home Health (A57311) (cms.gov)
11. LCD - Physical Therapy - Home Health (L33942) (cms.gov)
12. Article - Ankle-Foot/Knee-Ankle-Foot Orthoses - Policy Article (A52457) (cms.gov)
13. LCD - Ankle-Foot/Knee-Ankle-Foot Orthosis (L33686) (cms.gov)
14. LCD - Wheelchair Options/Accessories (L33792) (cms.gov)
15. Article - Wheelchair Options/Accessories - Policy Article (A52504) (cms.gov)
16. LCD - Wheelchair Seating (L33312) (cms.gov)
17. NCD - Assessing Patient's Suitability for Electrical Nerve Stimulation Therapy (160.7.1) (cms.gov)
18. LCD - Canes and Crutches (L33733) (cms.gov)
19. Article - Canes and Crutches - Policy Article (A52459) (cms.gov)
20. LCD - Cervical Traction Devices (L33823) (cms.gov)
21. Article - Cervical Traction Devices - Policy Article (A52476) (cms.gov)

NCQA UM Element A Clinical Criteria for UM Decisions

Clinical Resources

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ADDITIONAL RESOURCES

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3. CMS. Medicare claims processing manual. Chapter 20 – Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS). Centers for Medicare and Medicaid Services (CMS). Updated May 12, 2022. Accessed August 5, 2022. https://www.cms.gov/Regulations- and-Guidance/Guidance/Manuals/Downloads/clm104c20.pdf
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Policy History

Date	Update
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Experimental and Investigational Services and Devices

Fulcrum Clinical Guidelines **Experimental and Investigational Services and Devices**	**Original Date: June 2018 (NIA)** **January 2018 (Fulcrum)**
Physical Medicine – Clinical Decision Making	**Last Revised Date: January 2025**
Guideline Number: CLINUM 109	**Implementation Date: February 2025**

Policy Statement

This policy will be used to provide a listing of procedures considered experimental, investigational by any physical medicine practitioner. Services listed in the policy are not eligible for reimbursement. Coverage is subject to the terms of an enrollee's benefit plan. To the extent there is any inconsistency between this medical policy and the terms of an enrollee's benefit plan, the terms of the enrollee's benefit plan documents will always control. Investigational services are not covered under enrollee's health plan.

Procedure

1. A service is considered experimental/investigation if **any** of the following criteria is met:
   - The services, procedures, or supplies requiring Federal or other Governmental body approval, such as drugs and devices, do not have unrestricted market approval from the Food and Drug Administration (FDA) or final approval from any other governmental regulatory body for use in treatment of a specified condition. Any approval that is granted as an interim step in the regulatory process is not a substitute for final or unrestricted market approval.
   - There is insufficient or inconclusive medical and scientific evidence to evaluate the therapeutic value of the service, procedure, or supply.
   - There is inconclusive medical and scientific evidence in peer-reviewed medical literature that the service, procedure, or supply has a beneficial effect on health outcomes.
   - The service, procedure, or supply under consideration is not as beneficial as any established alternatives.
   - There is insufficient information or inconclusive scientific evidence that, when used in a non-investigational setting, the service, procedure, or supply has a beneficial effect on health outcomes or is as beneficial as any established alternatives.
2. Experimental and investigational services include the use of a service, procedure, or supply that is not recognized as standard clinical care for the condition, disease, illness, or injury being treated. A service, procedure, or supply includes, but is not limited to the diagnostic service, treatment, facility, equipment, or device. This organization will determine whether a service, procedure, or supply is considered experimental and investigational.
3. The following is a partial listing of experimental and investigational services:
   - Advanced BioStructural Correction (ABC)
   - Alphabiotics
   - Applied Kinesiology or any of its derivations [1]
   - Applied Spinal Biomechanical Engineering
   - BioEnergetic Synchronization Technique (B.E.S.T) [2]
   - Blood Flow Resistance Training [3-6]
   - Chiropractic Biophysics (CBP, [7] Clinical Biomechanics of Posture, CBP Mirror Image Technique [8])
   - Chiropractic services directed at controlling progression and/or reducing scoliosis, including but not

limited to the SpineCor brace [9] and CLEAR scoliosis treatment

- Coccygeal Meningeal Stress Fixation
- Cold Laser Therapy
- Computerized muscle testing or analysis
- Cupping [10-13]
- Craniosacral Therapy (CST)[14], including the Upledger Technique
- Directional Non-force Technique [15]
- Dry Needling [16]
- Hako-Med electrotherapy (horizontal electrotherapy).[17]
- Hippotherapy [18-24]
- Automated Impulse adjusting instrument
- Intersegmental traction and Autotraction[25,26]
- Kinesio taping [27-34] (Elastic Therapeutic Taping)
- Live Cell Analysis or hair analysis[35,36]
- Manipulation under Anesthesia (MUA)[37,38]
- Moire Contourographic Analysis[39]
- Nambudripad's Allergy Elimination Technique (NAET)/ other Allergy Testing[40]
- National Upper Cervical Chiropractic Association (NUCCA technique)[41] / Grostic technique
- Network Chiropractic, NeuroEmotional Technique (NET)[42,43]
- Neural Organizational Technique, Contact Reflex Analysis (CRA),[44] Whole System Scan
- Neurocalometer, Nervoscope, Nerve Conduction Velocity, Surface EMG,[45] Paraspinal Electromyography,[46] Spinoscopy or other nerve conduction or temperature differential testing for non-specific neck and back pain[47,48]
- Nimmo Receptor-Tonus method[49]
- Pettibon, including, but not limited to wobble chair/board treatment and posture pump[50-55]
- Preventive Care, Corrective Care
- Pro-Adjuster
- Sacro Occipital Technique, Neurocranial Restructuring (NCR),[56] Cranial Manipulation
- Sound Assisted Soft Tissue mobilization[57]
- Spinal Diagnostic Ultrasound[58]
- Repeat imaging to determine the progress of conservative treatment
- Thermography[59]
- Treatment for brachioradial pruritis
- Vascular Studies, including, but not limited to, Doppler ultrasound analysis and plethysmography
- VAX-D,60 Lordex, LTX3000, DRX-9000, DRS (Decompression Reduction Stabilization System), or other back traction devices charged at a higher rate than mechanical traction (97012)
- Whole Body Vibration (WBV),[61-63] Vibration Plate, Vibration Therapy
- Any lab work for which the office is not CLIA Certified or falls outside of the scope of practice, including, but not limited to: drug testing, therapeutic drug assays, and organ or disease oriented panels

4. Guidelines
   i) If such services are to be provided, the practitioner will inform the member, in writing, that such services will be the member's responsibility. None of these services are to be performed in lieu of an appropriate examination or without consideration of an appropriate referral.
   ii) There is limited scientific evidence that the use of experimental, investigational, and unproven services

provides an improved or more accurate diagnosis, nor do they result in an improved clinical outcome.

iii) Scientific literature will continue to be reviewed and any significant changes in published literature will be taken into consideration for modification of this policy.

5. Exclusions/Limitations: Refer to enrollee's Certificate of Coverage or Summary Plan Description. Coverage is subject to the terms of an enrollee's benefit plan. To the extent there is any inconsistency between this medical policy and the terms of an enrollee's benefit plan, the terms of the enrollee's benefit plan documents will always control. Investigational services are not covered under enrollee's health plan.
6. Removal of a service from the Experimental and Investigations Policy
   a) At least annually, a review of the current literature will be evaluated to determine if there is additional research in support of any of the services listed under this policy. This evaluation will include the following criteria:
      i) Safety – Is the potential benefit superior to the potential harm?
      ii) Health Outcomes – Is there evidence the service will provide, at minimum, equal outcomes and at best, superior outcomes to currently available services?
      iii) Patient Management – Will the service improve clinical decision making?
      iv) Clinical Performance – Is the reliability as well as predictive value of the service equal or superior to the current "gold standard" for such services?
      v) Cost-effectiveness – Is the service equal to or lower cost than currently utilized services for similar diagnosis and treatment?
7. If the service appears to be safe and cost-effective, Fulcrum will present these results to our health plan partners for consideration of coverage and/or payment. Final authority for such coverage determinations rests with the health plan.
8. All criteria will be based on peer-reviewed scientific literature and internationally and nationally accepted and published guidelines. Peer-reviewed scientific studies must be published in or accepted for publication by medical journals meeting national requirements for scientific publication (http://www.icmje.org/). The medical literature must meet the National Institutes of Health Library of Medicine standards for indexing (https://www.nlm.nih.gov/). Medical journals that publish most of their scientific manuscripts by the editorial staff of a journal will not be considered for review. If the majority of funding for research is published by the device manufacturer or organization sponsoring a technique, the results will not be considered for review.
9. Findings:
   a) Professional societies have published position statements concluding that diagnostic spinal ultrasound is investigational for non-operative spinal and paraspinal conditions in adults. The 2019 policy statement of the American Institute of Ultrasound in Medicine indicates: "There is insufficient evidence in the peer-reviewed medical literature establishing the value of non- operative spinal/paraspinal ultrasound in adults for diagnostic evaluations of conditions involving the intervertebral disks, facet joints and capsules, and central nerves… [A]t this time, the use of ultrasound in diagnostic evaluations, screening, or monitoring of therapy for these conditions has no proven clinical utility and should be considered investigational. Ultrasound may, however, be used as a guidance modality for certain spinal injections."[64]
   b) There is insufficient peer-reviewed published scientific evidence that computerized muscle testing leads to better patient outcomes. There is insufficient evidence to support any specific therapeutic effect of craniosacral therapy. While there is emerging evidence for the effectiveness of whole-body vibration in treating some medical conditions, the evidence for whole body vibration as a treatment for low back pain (LBP) remains equivocal.
   c) A 2015 systematic review[65] found that that low level laser therapy is an effective method for relieving pain in non-specific chronic low back pain patients. However, no significant treatment effect was identified for disability scores or spinal range of motion outcomes. Guidelines from the North American

Spine Society (2020)[66] report there is fair evidence to suggest that laser therapy combined with exercise provides better short-term relief of low back pain than either therapy alone. In addition, they report no short-term benefit of laser therapy when compared with exercise alone. Current studies supported by larger sample sizes with longer follow-up was recommended. In a 2009 study, Yeldan and colleagues report no statistically significant differences between the placebo LLLT and LLLT groups on shoulder function in subacromial impingement syndrome.[67] Ay and colleagues found "no differences between laser and placebo laser treatments on pain severity and functional capacity in patients with acute and chronic low back pain caused by LDH [lumbar disc herniation]."[68] Furthermore, both a 2016 Cochrane review[69] and 2017 meta-analysis[70] report limited effectiveness of low-level laser therapy in carpal tunnel syndrome management.in carpal tunnel syndrome management.in carpal tunnel syndrome management. A 2013 study examined the effectiveness of LLLT in reducing acute and chronic neck pain. The authors concluded, "This systematic review provided inconclusive evidence because of significant between-study heterogeneity and potential risk of bias. The benefit seen in the use of LLLT, although statistically significant, does not constitute the threshold of minimally important clinical difference."[71] The best available current evidence does not support the effectiveness of low level laser therapy as a therapy for patients with knee osteoarthritis.[65]

d) Similarly, there is insufficient evidence to support the clinical value of the Pettibon System. Posture Pump is deemed experimental and investigational because the effectiveness of this device has not been proven by adequate scientific studies, published in peer-reviewed scientific journals. There is insufficient evidence to support the clinical value of the Therapeutic (Wobble) Chair/Board.
e) The appropriateness and effectiveness of chiropractic manipulation as a preventive or maintenance therapy has not been established by clinical research and is not covered.
f) Thermography has not been shown to provide sufficient, reliable characterizing information about neurologic dysfunction or deficit to accept it as a proven evaluative procedure for the clinical diagnosis or characterization of: neck or back pain; musculoskeletal pain; entrapment neuropathy; headache; or transient cerebral ischemia and stroke. High-density surface electromyography (HD-sEMG), surface scanning EMG, paraspinal surface EMG, or macro EMG are considered experimental and investigational as a diagnostic test for evaluating low back pain or other thoracolumbar segmental abnormalities, such as soft tissue injury, intervertebral disc disease, nerve root irritation and scoliosis, and for all other indications because the reliability and validity of these tests have not been established. Surface EMG devices are also experimental and investigational for diagnosis and/or monitoring of nocturnal bruxism and all other indications because the reliability and validity of these tests have not been demonstrated. The Neurophysiologic Pain Profile (NPP) and the spine matrix scan (lumbar matrix scan) are considered experimental and investigational because the reliability and validity of these tests has not been established.
g) There is insufficient evidence to conclude that nerve conduction studies are beneficial for health outcomes in patients with non-specific neck or back pain. Non-invasive automatic or portable nerve conduction monitoring systems that test only distal motor latencies and conduction velocities are unproven and not medically necessary for the purpose of electrodiagnostic testing.
h) Plethysmography is used to diagnose deep vein thrombosis[72,73] and arterial occlusive disease.[74] Plethysmography is used as the sole diagnostic modality for these conditions or as an initial evaluation to determine the need for venography or arteriography. Body Plethysmography evaluates total lung capacity and residual volume.[75] Since treatment of cardiovascular and lung conditions falls outside of the scope of chiropractic, patients should be referred for testing if these conditions are suspected.

Regulatory, Accreditation and Resources

Fulcrum Provider Portal: https://fulcrumproviderportal.com
Medicare NCD & LCD

State Statutes
42 U.S.C. section 300gg-8
26 U.S.C. section 9815 (a)(1).
29 U.S.C. section 1185d (a)(1)
MN Statute 62M.072
MN Statute 62Q.525
MN Statute 62Q.526
Minnesota Rule 4685.0100 Subp.6A
Minnesota Rule 4685.0700 Subp.4F
WI Statute 632.855
IA Code 514C.26
Certificates of Coverage/Plan Documents/Summary Plan Descriptions

Clinical Resources

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ADDITIONAL RESOURCES

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Policy History

Date	Update
02/27/2018	New Document
02/27/2018	Approved by Clinical Policy Committee
2/28/2018	Approved by UM Subcommittee
3/11/2021	Approved by Clinical Policy Committee
3/18/2021	Approved by UM Subcommittee
3/17/2022	Approved by Clinical Policy Committee
3/29/2022	Approved by UM Subcommittee
03/21/2023	Approved by Clinical Policy Committee
05/02/2023	Approved by UM Subcommittee
12/07/2023	Approved by Clinical Policy Committee
12/19/2023	Approved by UM Subcommittee
03/07/2024	Approved by Clinical Policy Committee
03/15/2024	Approved by Utilization Management Subcommittee
01/23/2025	Approved by Clinical Policy Committee
02/04/2025	Approved by Utilization Management Subcommittee

Lack of Information

Fulcrum Health, Inc	
Clinical guidelines **Lack of Clinical Information**	**Original Date: November 2018**
Physical Medicine – Clinical Decision Making	**Last Revised Date: January 2025**
Guideline Number: UM031	**Implementation Date: February 2025**

Policy Statement

Review decisions will be made on the clinical information obtained by Fulcrum at the time of the review determination. Fulcrum will request additional clinical information from the requesting provider when it is necessary to render a medical decision. Providers and members shall be notified in a timely manner that a request for authorization of services includes insufficient information to complete a medical necessity review and additional information should be submitted. The policy outlines procedural time frames, what occurs, when necessary, information is not provided within the specified time frames, and processes by which an adverse determination occurs due to lack of information

Procedure

Requests for authorization of services must include clinical information sufficient to demonstrate medical necessity. If requests for services are not accompanied by sufficient information to verify that clinical criteria have been met, a request for additional information will be issued to the attending health care professional/provider, and the case will be pended for a specified period of time.

1. When more information is required to complete the medical necessity review, Fulcrum tries to contact the provider at least three (3) times by multiple methods and dates. Methods are:
   a) Attempt 1: provider portal web note or fax on day 1,
   b) Attempt 2: RFI letter mailed on day 2
   c) Attempt 3: phone call on day prior to due date.
   d) The due date is stated in the communication.
2. When requesting information, staff will:
   a) Identify self by name, title, and organization
   b) Identify member by name, date of birth and insurance identification number
   c) Describe the information that is needed for completion of the review
   d) Provide the date that the information is needed
   e) Provide a call back number if questions arise
   f) Provide instructions for provider portal entry or a fax number for submission of the information
3. Staff will document in the QConnect (UM System):
   a) Information needed for clinical review
   b) Provide the date that the information is needed
   c) Provide a call back number if questions arise
   d) Provide instructions for submission of information.
4. For non-urgent preservice requests:
   a) For MN Fully Insured & Self -Insured Commercial Plans, Fulcrum gives written and/or electronic notification of the non-urgent preservice decision to members and providers within five (5) business days of the request. (MN Statute 62M.05 Subd3a).
   b) For non-MN Commercial & Exchange, Fulcrum gives written and/or electronic notification of the non-urgent preservice decision to members and providers within 15 calendar days of the request. (NCQA UM 5 A4).

c) For Medicare and MN Medicaid, Fulcrum gives written and/or electronic notification of the non-urgent preservice decision to the member and provider within 14 calendar days of the request (NCQA UM5 A5).

5. For urgent authorizations (not applicable to physical medicine providers)
   a) For MN Fully Insured & Self-Insured commercial Plans, urgent authorization must be made within 48 hours and must include at least one business day after the initial request. (MN Statute 62M.05, Subd. 3b).
   b) For Medicare, non-MN commercial Fully Insured and Self-Insured, and MN Medicaid, urgent authorization decisions must be made within 72 hours of the request and include written and/or electronic notification to member and provider.
   c) Post Service reviews are completed within 30 Calendar days. (NCQA UM 5 A6) with written and/or electronic notification to the provider and member. Member notification is not required if the member is not at financial risk.
6. Review determination (NCQA UM6 A):
   d) Upon receipt of additional information, the reviewer completes the medical necessity review and authorizes the request if criteria are met.
   e) When requested information is not received, a determination is made by the clinical peer reviewer based on the available information. If denied, the UM Coordinator sends the adverse determination letter to the member and provider, with denial reason as lack of information. The letter must indicate the specific information needed in the adverse determination notice.
   f) RFI validation is defined as follows (occurring after the RFI receipt date but on or before decision date):
      a. Assessments entered in whole or in part
      b. verbal or web note from provider stating that they do not have the information requested
      c. Medical records attached to the episode
      d. Incorrect clinical information that was not available on the initial submission

Regulatory, Accreditation and Resources

NCQA UM 5 and UM 6
MN Statute § 62M.04 Subd.4
MN Statute § 62M.05, Subd.4
Medicare CMS Part C & D Enrollee Organization/coverage Determinations and Appeals Guidance

Policy History

Date	Update
10/09/2018	Approved by UM Subcommittee
10/09/2019	Approved by UM Subcommittee
10/20/2020	Approved by UM Subcommittee
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03/07/2024	Approved by Clinical Policy Committee
03/15/2024	Approved by Utilization Management Subcommittee
01/23/2025	Approved by Clinical Policy Committee
02/04/2025	Approved by Utilization Management Subcommittee

Passive Modality Utilization

Fulcrum Health, Inc	
Clinical guidelines **Passive Modality Utilization**	**Original Date: June 2018**
Physical Medicine – Clinical Decision Making	**Last Revised Date: January 2025**
Guideline Number: CLINUM102	**Implementation Date: February 2025**

Policy Statement

Fulcrum does not support the use of multiple passive treatments for the care of musculoskeletal pain within the scope of network practitioners. Most passive treatments have similar physiological effects related to pain control and reduction of inflammation. The use of treatments with duplicative physiological effects is unnecessary and inappropriate. Multiple passive treatments have not been shown to improve or accelerate patient health outcomes.

Scope

Physical medicine participating network practitioners, including rendering chiropractors, physical therapists, occupational therapists, speech therapists, and therapist assistants as applicable. This policy also applies to out of network practitioners as determined and delegated by the health plan.

Definitions

Modality is defined as any group of agents that may include thermal, acoustic, radiant, mechanical, or electrical energy to produce physiologic changes in tissues for therapeutic purposes. Modalities affect tissue at the cellular level.

Multiple modalities are defined as the use of and/or billing of two or more physical medicine modalities each visit or during the same session to the same region.

Passive Treatment is applied by the provider or in a clinical setting and does not involve active participation by the patient.

Procedure is a service provided to increase the functional abilities in self-care, mobility, or safety.

Procedure

1. The following is a list of procedures and modalities considered to be passive treatment:
   a) Chiropractic Manipulative Therapy (98940, 98941, 98942, 98943)
   b) Acupuncture with and without electrical stimulation (97810, 97811, 97813, 97814)
   c) Thermal and light therapy - Hot/cold (97010), diathermy (97024), microwave (97020), infrared (97026), ultraviolet (97028), ultrasound (US) (97035), paraffin bath (97018) and whirlpool (97022).
   d) Electrical therapy - High volt, low volt, interferential current, transcutaneous electrical nerve stimulation (TENS) (97014 and 97032).
   e) Mechanical - mechanically assisted and often a sustained pull of the spine or limb, such as traction (97012).
   f) Therapeutic massage and manual therapy (97124 and 97140)—Manual therapy includes Active Release Technique, trigger point therapy, myofascial release, mobilization/manipulation, manual lymphatic drainage, and manual traction.

2. Appropriate use of passive treatment:
   a) Passive treatment modalities may be utilized in the initial period of an episode of treatment or exacerbation of a sub-acute or chronic condition for pain control, reduction of inflammation, or reduction of muscle spasm. As a condition progresses, passive care should be replaced by active treatment modalities, such as therapeutic exercise. Insufficient evidence exists to support the continued use of passive treatment as a means for improved clinical outcomes.
   b) The following must be met before recommending needle acupuncture as a reimbursable passive procedure:
      i) The chiropractor utilizing needle acupuncture must meet specific state requirement for practicing acupuncture and be credentialed by Fulcrum.
      ii) The procedure must not be clinical redundant (provide the same physiological effect such as reducing spasm or inflammation) with other modalities/therapies applied to the same area other than manipulation.
   c) Passive treatment is clinically appropriate and/or necessary in the conservative management of neuromusculoskeletal conditions when:
      i) There are no contraindications to the intervention.
      ii) Self-administration is implausible or places the patient at risk of harm.
      iii) Used primarily during the initial period of an episode of treatment.
      iv) Used to support an active care approach (i.e., therapeutic exercise)
      v) Used for a particular condition for which there is an evidence-basis of significant benefit.
   d) Passive treatment is NOT clinically appropriate and/or necessary when:
      i) Patient safety is jeopardized by the application of the modality.
      ii) The treatment can safely and effectively be administered by the patient or another individual.
      iii) Used during a course of treatment, which continues beyond the initial period.
      iv) Used as the primary or sole therapy.
      v) Greater than one passive treatment is used involving the same body region(s).
      vi) Used largely for the comfort and convenience of the patient.
      vii) Used as part of the routine office protocol.
3. Exclusions
   a) The use of chiropractic manipulation (98940-98943) is not considered a duplication of service or physiological effect when used in conjunction with passive treatment, except when the National Correct Coding Initiative (NCCI) edits require that the manual therapy techniques be performed in a separate anatomic site than the chiropractic adjustments in order to be reimbursed separately.
   b) The limited number of studies and the quality of research evidence (designs, methodologies, sample sizes, variation of interventions, and outcomes measured) do not permit confident judgments about the effectiveness and safety of manual therapy interventions for the treatment of non-musculoskeletal disorders. As a result, evidence of effectiveness is lacking, and/or inconclusive. The treatment of non-musculoskeletal disorders using manual therapy interventions is unproven.
4. Documentation requirements:
   a) The treatment plan or plan of care must include the clinical rationale for each service, a description of the service, the area of the body the service will be provided, goals for each service, and a time component, if indicated.
   b) Applicable contraindications for passive modalities (e.g. ultrasound therapy) should be considered.

Regulatory, Accreditation and Resources

Medicare NCD & LCD

i. Article - Chiropractic Services – Medical Policy Article (A57889) (cms.gov) (01/01/2020) (IL, MN, WI, NY, CT, ME, MA, NH, RI, VT)

ii. LCD - Chiropractic Services (L37387) (cms.gov) (09/29/2021) (AL, GA, TN, SC, VA, WV, NC)
iii. LCD - Chiropractic Services (L37254) (cms.gov) (01/26/2023) (KY, OH)

Medicare Billing and Coding: Chiropractic Services

1. Article - Billing and Coding: Chiropractic Services (A58345) (cms.gov) (10/01/2020) (WY, CO, NM, TX, OK, AR, LA, MS, DE, DC, NJ, PA, MD)
2) Article - Billing and Coding: Chiropractic Services (A56273) (cms.gov) (07/07/20223) (IA, KS, MO, NE, IN, MI)
3) Article - Billing and Coding: Chiropractic Services (A56616) (cms.gov). (10/10/2019) (AK, GA, TN, SC, VA, WV, NC)
4) Article - Billing and Coding: Chiropractic Services (A56455) (cms.gov) (11/16/2023) (KY, OH)
5) Article - Billing and Coding: Chiropractic Services (A58412) (cms.gov) (10/01/2020) (FL, VI, PR)
6) Article - Billing and Coding: Chiropractor Services (A57914) (cms.gov) (01/01/2020) (AL, OR, WA, AZ, ND, SD, UT, WY, MT)
7) NCCI for Medicare | CMS

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Policy History

Date	Update
November 2023	New Policy
12/07/2023	Approved by Clinical Policy Committee
12/19/2023	Approved by UM Subcommittee
03/07/2024	Approved by Clinical Policy Committee
03/15/2024	Approved by Utilization Management Subcommittee
01/23/2025	Approved by Clinical Policy Committee
02/04/2025	Approved by Utilization Management Subcommittee