National Imaging Associates, Inc.*

2023 NIA Clinical Guidelines For Medical Necessity Review

PHYSICAL MEDICINE

Effective July 1, 2023 – July 1, 2024

*National Imaging Associates, Inc. (NIA) is a subsidiary of Evolent Health.

Magellan HEALTHCARE®

Guidelines for Clinical Review Determination

Preamble

Magellan is committed to the philosophy of supporting safe and effective treatment for patients. The medical necessity criteria that follow are guidelines for the provision of diagnostic imaging. These criteria are designed to guide both providers and reviewers to the most appropriate diagnostic tests based on a patient's unique circumstances. In all cases, clinical judgment consistent with the standards of good medical practice will be used when applying the guidelines. Determinations are made based on both the guideline and clinical information provided at the time of the request. It is expected that medical necessity decisions may change as new evidence-based information is provided or based on unique aspects of the patient's condition. The treating clinician has final authority and responsibility for treatment decisions regarding the care of the patient.

Guideline Development Process

These medical necessity criteria were developed by Magellan Healthcare for the purpose of making clinical review determinations for requests for therapies and diagnostic procedures. The developers of the criteria sets included representatives from the disciplines of radiology, internal medicine, nursing, cardiology, physical therapist (PT), and other specialty groups. Magellan's guidelines are reviewed yearly and modified when necessary following a literature search of pertinent and established clinical guidelines and accepted diagnostic imaging practices.

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Guideline Number: NIA_CG_603	**Implementation Date: July 2023**

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 at the end of this document, 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.

National Imaging Associates 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]

INDICATIONS

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

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- Have written referral from primary care practitioner or other non-physician practitioner (NPP) if required by state guidelines.
- 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]
- 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:
    - The following methods are generally accepted measures that may be considered to support a significant delay:
        - Standardized scores at or below the 10th percentile in at least one subtest area for the patient's age.[6]
        - 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]
        - 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]
- 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.
- 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.
- Any time standardized testing cannot be completed, the documentation must clearly state the reason formal testing could not be done.
    - 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.
    - 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 (Activities of Daily Living) deficits and the medical need for skilled services. The documentation must clearly state the reason formal testing could not be completed.
    - 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.

    - In the case of feeding difficulties, the notes must clearly indicate a functional feeding delay as a result of underlying impairments.
        - This may include gagging/choking, oral motor or upper extremity coordination deficits, or maladaptive behaviors due to a food intolerance/aversion preventing adequate oral intake that contribute to malnutrition or decreased body mass index.
        - 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.
        - Parent report of limited food choices is not adequate to support the medical need for feeding therapy.
        - 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 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.
- 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, NIA Clinical Guideline 606-01 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).
- 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 change in member status or restricted age range of the testing tool, the provider should explain the reason for the change.
- 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.
- 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]
    - 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.
    - 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.
- 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]
    - 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.
- 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]
- Frequency and duration of skilled services must also be in accordance with the following:
    - 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.
        - 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
            - Letter of medical need from the prescribing provider documenting the member's rehabilitation potential for achieving the goals identified.
            - Therapy summary documenting all of the following:
                - Purpose of the high frequency requested (e.g., close to achieving a milestone)
                - Identification of the functional skill which will be achieved with high frequency therapy

        - Specific measurable goals related to the high frequency requested and the expected date the goal will be achieved.
    - 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:
        - The member is making very good functional progress toward goals
        - The member is in a critical period to gain new skills or restore function or is at risk of regression.
        - 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.
        - The member has complex needs requiring ongoing education of the responsible adult.
    - 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]:
            - 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.
            - 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.
            - 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.
            - 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 basic 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.
    - All requested frequencies must be supported by skilled treatment interventions regardless of level of severity of delay.[18]
- 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.

- 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:
    - The patient's current level of function, any conditions that are impacting his/her ability to benefit from skilled intervention.
    - 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 is sustained over time.
    - 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.
    - 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.
    - 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.
- Maintenance Level/Prevent Deterioration
    - 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.
    - 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
    - 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:
        - Progress has slowed or stopped, but documentation supports that ongoing skilled therapy is required to maintain the progress made or prevent deterioration.
        - The submitted documentation shows that the member may be making limited progress toward goals or that goal attainment is extremely slow.
        - 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).
        - 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.
- 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:
    - Member no longer demonstrates functional impairment or has achieved goals set forth in the treatment plan or plan of care
    - Member has returned to baseline function
    - Member 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
    - Member has adapted to impairment with assistive equipment or devices
    - Member is able to perform ADLs with minimal to no assistance from caregiver
    - Member has achieved maximum functional benefit from therapy in progress or will no longer benefit from additional therapy
    - Member 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
    - Testing shows member no longer has a developmental delay
    - Plateau in response to therapy/lack of progress towards therapy goals
    - Non-compliance due to poor attendance and with member or responsible adult, non-compliance with therapy and home treatment program
    - Member 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.
- 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.
- 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.
- 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]

BACKGROUND

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 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.

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]

POLICY HISTORY

Date	Summary
December 2022	• Modified the standardized testing requirements • Clarified requirements for picky eaters • Added goals should be written in SMART format • Clarified the need for clinical update documentation

	• Added the section for goals in the Maintenance Level/Prevent Deterioration section • Clarified the formal testing section and added additional references to support the accepted measures of a significant delay • Minor editorial changes
December 2021	• Added “General Information” statement • Added “resulting in adverse determinations” within the EPSDT statement for clarification • Added “if required” for written referral under the Indication for evaluation and treatment section • Added medical or cognitive status exceptions under the Indications for evaluation and treatment section • Added orthopedic diagnosis expectations under the Indication for evaluation and treatment section • Added clarification for re-evaluation and retesting requirements • Added focus of intervention under intervention section • Added clarification of high, moderate, and low frequency under frequency and duration for skilled services section as this was adapted from the Superior Health Plan Policy • Added Maintenance Level/Prevent Deterioration section • Added clarification for Discontinuation of therapy services section
October 2020	• Added indication of home program compliance for max benefit of therapy as part of updated POC • Added additional resource which supports episodic care and appropriate frequencies • Added EPSDT language in policy statement section • Added annual tests be performed at a minimum of once a year and formalized progress assessment with updated measures at routine intervals may also be needed prior to the one-year mark from previous testing. • Removed “physician-prescribed” from the medical necessity definition in the background • Added qualifier for proof of skilled treatment for requested frequencies regardless of level of severity of delay • Added clarification on need for documentation to support ongoing requested frequencies with showing effective outcomes and reasonable time frames • Added clarification for when test scores are within normal, yet functional delays are present • Added teletherapy to the policy statement

January 2020	• No content changes following review of the evidence base. Minor copyediting changes.
July 2019	• Definitions were moved to the background so pertinent information was readily available at the beginning of the document. • Existing definitions were revised to include greater detail with new definitions for *rehabilitative therapy* (for comparative purposes), *medical necessity* and *maintenance program* included. • Criteria for delay was revised to include clearer and more detailed specifications for functional delays, preferred scoring, and what is required in the absence of standardized testing. • Criteria for feeding delays were added. • Additional specifications included for linking testing to the treatment goals, inclusion of functional treatment goals, utilizing appropriate dosing of therapy and specifying skilled interventions.

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ADDITIONAL RESOURCES

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Reviewed/Approved by NIA Clinical Guideline Committee

GENERAL INFORMATION

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.

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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

Definition

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

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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

They 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 ceases to be of therapeutic value.

National Imaging Associates 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]

INDICATIONS

- Must have written referral from primary care practitioner or other non-physician practitioner (NPP) as permitted by state guidelines.
- 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.
- 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:
    - The following methods are generally accepted measures that may be considered to support a significant delay:
        - Standardized scores at or below the 10th percentile in at least one subtest area for the patient's age.[3]

        - 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]
        - 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]
- 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.
- 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.
- Any time standardized testing cannot be completed, the documentation must clearly state the reason formal testing could not be done.
- 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:
    - 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]
    - 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]
- Frequency and duration of skilled services must also be in accordance with the following:
    - 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.
    - 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.
    - 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.
    - All requested frequencies must be supported by skilled treatment interventions regardless of level of severity of delay.
    - Additional factors may be considered on a case-by-case basis.
- 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.
    - Treatment that requires the 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.
    - 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:
        - The patient's current level of function, any conditions that are impacting his/her ability to benefit from skilled intervention.
        - Objective measures of the patient's overall functional progress relative to each treatment goal as well as a comparison to the previous progress report.
        - 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.
        - 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.
        - 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.
    - 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.

- 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.
- 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.
- 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.
- 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:
    - 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.
    - 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.
    - 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.
- 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]
    - 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.
    - 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.
- 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.

POLICY HISTORY

Date	Summary
December 2022	• Updated indications – revised criteria for standardized testing • Revised language for maintenance programs • Revised language for patients with a language background different than rendering therapist and for patients exposed to more than one language • Clarified formal testing section and added references to support accepted measures for a significant delay • Updated references
December 2021	• Added “General Information” statement • Added “resulting in adverse determinations” to EPSDT statement • Reworded for clarity indication regarding bilingual patients (patients whose language background differs from rendering therapist) • Added criteria stating that treatment including goals for reading/literacy must have primary diagnosis of speech or language disorder with documentation support showing how

	services for reading/literacy require skills of a speech language pathologist
August 2020	• Changed guideline name to include 'rehabilitative': Outpatient Habilitative and *Rehabilitative* Speech Therapy • Added to definition of Habilitative and Rehabilitative Therapy • Criteria for delay was revised to include clearer and more detailed specifications for functional delays, preferred scoring, and what is required in the absence of standardized testing. • Additional specifications included for linking testing to the treatment goals, inclusion of functional treatment goals, utilizing appropriate dosing of therapy and specifying skilled interventions. • Moved coordination with school program to end of guideline. • Added EPSDT language in policy statement section • Added indication of home program compliance for max benefit of therapy as part of updated POC • Added ASHA guideline for discharge qualification due to behavior • Added teletherapy to the policy statement • Formatted and adjusted language to match the PT/OT habilitative guideline where applicable
January 2020	• Added the *italicized* clauses as follows: For bilingual patients whose primary language 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. Further, the assessment must contain appropriate tests and measures to clearly denote the presence that a communication *disorder is present in both languages*, as opposed to normal linguistic variations *or a language learning problem for the non-dominant language.*
July 2019	• Added the following definition for rehabilitative speech therapy: Rehabilitative Speech Therapy

	Treatments provided by a state-regulated speech therapist designed to improve, maintain, and prevent the deterioration of skills and functioning for daily living that have been lost or impaired. • Added the following to the definition of functional skills: 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 ceases to be of therapeutic value. • Speech therapy initial evaluation revised to require developmental delay or condition that has a standard/composite score that is ≥ 1.5 standard deviations below the mean • Clarified "picky eater" to state that for those 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 outpatient habilitative ST is not medically necessary

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ADDITIONAL RESOURCES

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Reviewed/Approved by NIA Clinical Guideline Committee

GENERAL INFORMATION

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.

National Imaging Associates, Inc.*	
Clinical guidelines **RECORD KEEPING AND DOCUMENTATION STANDARDS: PHYSICAL MEDICINE**	**Original Date: November 2015**
Physical Medicine – Clinical Decision Making	**Last Revised Date: August 2022**
Guideline Number: NIA_CG_606-01	**Implementation Date: July 2023**

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.

MEDICAL RECORD CONTENT REQUIREMENTS FOR ALL PATIENTS

GENERAL GUIDELINES

- 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.
- 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.
- Documentation should be complete and include the practitioner's signature and credentials, appropriately dated chart entries, and include patient identifications on

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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.
- Services must be documented in accordance with Current Procedural Terminology (CPT®) coding criteria (e.g., location (body region), time component, etc.).
- Adverse events associated with treatment should be recorded in the patient chart.

Clinical Documentation

- 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.
- 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.
- 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.
- 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]
- 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.
- Functional outcome assessment and/or standardized test results with raw scores, standardized scores, and score interpretation must be included.

- Detailed clinical observations, as well as prognosis and rehab potential, must be outlined.
- Contraindications to care must be listed with an explanation of their current management.
- School programs, including frequency and goals to ensure there is no duplication *(for Habilitative OT/PT/ST).*
- Information regarding child's involvement in home and community programs *(for Habilitative OT/PT/ST).*
- 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.

Treatment plan or Plan of Care
Include the following:

- 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.
- 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]
- Visits or units requested must not exceed the frequency and duration supported in the plan of care
- Frequency and duration of skilled services must also be in accordance with the following:
    - 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.
    - 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.
    - 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.
    - Additional factors may be considered on a case-by-case basis.
    - Requested frequency/duration must be supported by skilled treatment interventions regardless of level of severity of deficit or delay.
- 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.
- 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.
- 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.
- 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.

LACK OF INFORMATION

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.

CONFIDENTIALITY OF RECORDS

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.

BACKGROUND

Definition

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.

- 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 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 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 skilled licensed professional renders the service.
- 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.
- 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:

- **Contractual** – all covered medically necessary health care services are determined by the practitioner's contract with the payer and individual health plan benefits.
- **Scope of Practice** – medically necessary health care services are limited to the scope of practice under all applicable state and national health care boards.
- **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.
- **Patient Safety** – all health care services must be delivered in the safest possible manner.
- **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.
- **Setting** – all health care services must be delivered in the least intensive setting.
- **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.
- **Clinical Guidelines**– health care services are considered medically necessary if they meet all of the Clinical Guidelines of this organization.

POLICY HISTORY

Date	Summary
August 2022	• Revised policy statement to include "documentation must contain evidence to support medical necessity and the need for skilled services…" • General Guidelines: Changed "network practitioner" to "practitioner" and "licensed chiropractor or rehabilitation therapist" to "licensed therapist • General Guidelines: described documentation requirements for all patients • "Clinical Documentation" heading replaced "Evaluation" heading • Clarified specific documentation requirements in the Clinical Documentation section • Clarified treatment plan/plan of care requirements

	• Removed Daily Treatment Note, Progress Note, Re-Evaluation, Utilization Review sections • Removed CPT Code and Complexity Level Charts • Removed reference to chiropractor throughout. • References updated.

December 2021	• Added "General Information" statement
	• Original Record Keeping and Documentation Standards guideline was split into two separate guidelines:
	  ○ Record Keeping and Documentation Standards: Physical Medicine
	  ○ Record Keeping and Documentation Standards: Chiropractic Care
	• Deleted "For patients with developmental delay" from section on Treatment Plan to broaden "Description of baseline functional status/limitations based on standardized testing administered or other assessment tools"
	• Added option of written letter from member when seeking services from new provider under the General Guidelines
	• Added requirement that initial evaluation must be performed by a licensed PT, OT, ST, MD, DO, or DPM
	• Added examples of returning to activities beyond normal daily living
	• Added that "units" requested must not exceed frequency and duration supported in POC
	• Clarified "if appropriate" regarding collaboration with other services/professionals within the updated POC elements
	• Changed to state that progress note should be performed every 30 days or 10 visits, whichever occurs first, to align with CMS guidelines
	• Clarified contents of progress notes
	• Added G2250 (New code, effective 1/1/2021)

October 2020	• Added teletherapy in the policy statement • Added start of care be listed on progress note requirements • Moved CPT codes to background • Added indication of home program compliance for max benefit of therapy as part of updated POC • Added accommodative language to be inclusive of chiropractic care in medical necessity definition • Added support for excessive frequency/duration requests being in accordance with accepted standard of practice

	• Added parenthetical evaluation section to clarify that treatment should not focus on return to activities beyond normal daily living (sport/recreation/work) • Added that visits requested must not exceed the frequency and duration supported in the plan of care • Added qualifier for proof of skilled treatment for requested frequencies regardless of level of severity of delay
January 2020	• No edits made to guideline in response to the review of the evidence base
July 2019	• Definitions moved to the background so that relevant information is more readily available • Organization of material into subcategories as well as formatting CPT code tables and deleting repetitive information for consistency and readability • Clarification and grammar edits to provide greater detail • Additional caveats for medical necessity/non-skilled interventions included as greater support for lack of skill denials • Updated references

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Reviewed/Approved by NIA Clinical Guideline Committee

GENERAL INFORMATION

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.

National Imaging Associates, Inc.*	
Clinical guidelines **CHIROPRACTIC INFANT CARE POLICY**	**Original Date: April 2016**
Physical Medicine – Clinical Decision Making	**Last Revised Date: August 2022**
Guideline Number: NIA_CG_611	**Implementation Date: July 2023**

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
All of the following apply:

- 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. If the infant patient is not showing clinically significant improvement, as evidenced by progress toward measurable goals, after a two-week trial of chiropractic care, no additional chiropractic care is indicated and referral may be appropriate.[1]

- 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.

- 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]

* National Imaging Associates, Inc. (NIA) is a subsidiary of Magellan Healthcare, Inc.

- 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.

- The following are considered unsafe or unproven services:
  - 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.
  - 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
  - The use of the following services:

    - CPT code 97012 – Mechanical traction
    - CPT code 97014 – Unattended electrical stimulation
    - CPT code 97032 – Attended electrical stimulation
    - HCPCS code G0283 – Electrical stimulation
    - CPT code 97035 – Ultrasound
    - CPT code S9090 or any code used to bill low level laser

- The following codes will require peer review of clinical documentation to determine medical necessity:

  - CPT code 97110 – Therapeutic exercise
  - CPT code 97112 – Neuromuscular reeducation
  - CPT code 97530 – Activities of daily living
  - CPT code 98942 – 5-region chiropractic manipulative therapy
  - CPT code 98943 – Extra-spinal chiropractic manipulative therapy
  - CPT code 97124 – Massage therapy
  - CPT code 97140 – Manual therapy
  - All X-rays

This organization has the ultimate authority to determine if treatment is medically necessary and appropriate.

BACKGROUND

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 "[p]hysical 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 "[m]usculoskeletal 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).

POLICY HISTORY

Date	Summary
August 2022	No content changes
December 2021	Added "General Information" statement. No substantive clinical changes have been made.
October 2020	No content changes
January 2020	No content changes following review of the evidence base. Minor copyediting changes.
June 2019	This guideline has been reviewed. No substantive clinical changes have been made.

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Reviewed/Approved by NIA Clinical Guideline Committee

GENERAL INFORMATION

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.

National Imaging Associates, Inc.*	
Clinical guidelines **PLAIN FILM X-RAYS**	**Original Date: April 2016**
Physical Medicine – Clinical Decision Making	**Last Revised Date: August 2022**
Guideline Number: NIA_CG_610	**Implementation Date: July 2023**

Policy Statement

The use of plain films is medically necessary when clinical findings dictate their utilization. Films are not indicated to identify unsuspected contraindications to chiropractic manipulation, view postural changes and biomechanics, or identify subluxations. Insufficient scientific evidence exists to support the use of routine plain film radiographs as a means for improved clinical outcomes in spinal disorders. There is insufficient clinical research to support improved clinical outcomes when radiographs are a part of a routine component of the initial evaluation or ongoing treatment. This organization has adopted the Diagnostic Imaging Practice Guidelines for Musculoskeletal Complaints in Adults.[1-4] These guidelines represent the official position of the Council on Chiropractic Guidelines and Practice Parameters in matters related to the use of diagnostic imaging in the chiropractic profession.

The use of full spine radiographs, except for the clinical investigation and diagnosis of scoliosis, is not supported by clinical research.

Initial Clinical Reviewers (ICRs) and Physician Clinical Reviewers (PCRs) must be able to apply criteria based on individual needs and based on an assessment of the local delivery system.

Purpose

This policy will be used to support the medical necessity of plain film radiographs by chiropractic providers within the first 30 days of care.

Scope

This policy will apply to all participating network chiropractic practitioners.

Definition

Plain films:

Spinal or extremity radiographs used as a diagnostic tool by chiropractors.

* National Imaging Associates, Inc. (NIA) is a subsidiary of Magellan Healthcare, Inc.

Guidelines

- An appropriate history and examination are required to determine if plain films are clinically indicated.

- Utilization of radiographs by chiropractors will not be reimbursed unless sufficient medical record documentation is submitted with claims to support the medical necessity of the film. The clinical record must clearly document the rationale for the x-rays, any suspected pathology, or what condition the chiropractor hopes to rule out. The use of plain films to rule out an unsuspected pathology is not clinically indicated.

- Routine use of radiographs as part of the initial evaluation or part of an ongoing treatment plan will not be reimbursed.

- The use of full spine radiographs for any diagnosis other than scoliosis is not considered medically necessary and will not be reimbursed.

- Contraindications to plain film x-rays include:
    - Infants (0 - 36 months)
    - Pregnancy or possible pregnancy
    - Obesity, if size precludes good radiographic resolution
    - Patient has positioning difficulty due to mental status or physical restrictions, which precludes good radiographic resolution
    - Children 3 to 18 years of age, except for investigation of suspected acute fracture, dislocation, infection, scoliosis, developmental defects, or a suspected pathology.

Requirements

- The clinical record must contain a written x-ray report within 5 business days from the date of service.

- The clinic must have all of the following:
    - A documented Quality Control Program inclusive of both imaging equipment and film processors
    - A documented Radiation Safety and As Low As Reasonably Achievable (ALARA) Program
    - Documented emergency policies, procedures, and equipment on site (i.e., automated external defibrillator (AED))
    - Documentation of current Basic Life Support (BLS) certification
    - Records of formal preventative maintenance program per original equipment specifications
    - A current (within 3 years) letter of state inspection, calibration report, or physicist's report

- At a minimum, an automatic processor must be used to develop all analog plain films.

Clinical Examples of Medically Necessary X-rays

- Investigation of suspected acute fracture
- Follow-up radiographs to monitor a healing fracture
- Investigation of suspected bony dislocation
- Evaluation of prior surgical site where manual based treatment may be applied (where no previous films are available for review)
- Suspected (patient history, pain characteristics and/or physical examination) malignancy, infection, systemic disease, or inflammatory spondyloarthropathology
- Precise quantification of clinically suspected active child or juvenile scoliosis
- Persistent (same or worse pain) after first month of treatment
- Significant history of drug or alcohol abuse, such as IV drugs, chronic alcoholism, or chronic use of steroids
- Adult with thoracolumbar, lumbar, or thoracic spine blunt trauma or acute injuries (falls, motor vehicle accidents [MVAs], motorcycle, pedestrian, cyclists, etc.)
- Adult with complicated (i.e., "red flag") low back pain (LBP), thoracic pain, or neck pain **and** indicators of contraindication to spinal manipulative therapy (SMT) (relative/absolute)
- Suspected inflammatory spondyloarthropathies[5], neoplasia, or infection
- Adult: in the absence of expected treatment response or worsening after 4 weeks of conservative treatment
- Adult with acute neck injury and positive CCSR (Canadian Cervical Spine Rule for Radiography in Alert and Stable Trauma Patients)
- Suspected lumbar degenerative spinal stenosis or spondylolisthesis if individual is greater than 50 years of age and/or has progressive neurological deficit – AP (or PA) and lateral lumbar views[4]
- Adult with recent unimaged blunt trauma to pelvis and unable to bear weight[1] – AP pelvis and lateral hip "frog leg" views[4]
- Acute neck pain with recent unimaged dangerous trauma; paresthesia in extremities; age greater than 65 years; or non-traumatic neck pain with radicular symptoms[1] – APOM, AP lower cervical and lateral neutral views[4]
- Adult with painful or progressive scoliosis[1] – Erect standing full spine (14x36) PA and lateral views in the absence of recent films.[4]
- Plain film x-rays may be appropriate when red flags suggest further screening for cancer, infection, or fracture. They may also be sufficient for the initial evaluation of individuals with the following red flags: age >70 years, a history of recent significant trauma, or risk of osteoporosis. Plain film x-rays may be appropriate but are usually not sufficient for clinical decision making without advanced imaging in the presence of other red flags. Radiographs are unreliable for assessment of bone mass changes before at least a 30%-50% loss. In healthy peri- and early postmenopausal women (age 45-64), consider using the Osteoporosis Self-Assessment Tool (OST score). The OST score considers only 2

variables: (weight in kg − age)/5. The cut-off for a positive test is <2, indicating this woman should be referred for DXA.[4]

- Current x-ray recommendations/guidelines for spinal and extremity disorders emphasize a focused history and physical examination, reassurance, initial pain management medications if necessary (acetaminophen or nonsteroidal anti-inflammatory drugs), and consideration of nonpharmacologic therapies (e.g., manipulation, exercise, etc.) without routine imaging in individuals with nonspecific neck and/or low back pain. Imaging is considered for those without improvement after 6 weeks and for those with clinical indicators of serious pathologies (red flags).

Plain film x-rays of the extremities may be indicated in the following circumstances:

- Significant history of recent trauma sufficient to cause fracture
- Significant history of repetitive stress to cause stress fracture
- Suspected stress (insufficiency) fracture[13]
- History or clinical findings of malignancy
- Previous surgery or fracture
- Suspicion of or confirmed inflammatory arthritis
- Evaluation of gross deformities
- Bruising, swelling, redness heat, indicating infection
- Lymphadenopathy
- Evaluation of developmental hip dysplasia in the pediatric population
- Evaluation of Leg-Calve-Perthes disease
- Evaluation of slipped capital femoral epiphysis in the pediatric population
- Evaluation of chronic hip pain, initial imaging

Plain film radiographs may be appropriate but are usually not sufficient for clinical decision making without advanced imaging (MR and/or CT) in the presence of other red flags including:

- Age < 20 years or > 50 years
- Failure to improve with care, no prior films
- Personal history of intravenous drug abuse
- History of malignancy
- Immune suppression
- Night pain (including when unrelated to movement)
- Pain at multiple sites
- Pain at rest
- Fever
- Structural deformity
- Systemic unwellness
- Unexplained weight loss

Spinal radiographs also have a role in evaluation of scoliosis and in postoperative evaluation of instrumentation and fusion. For the evaluation of scoliosis in children, radiographic decision-making and examinations should be performed in accordance with guidance published by the

American College of Radiology (ACR) and the Society for Pediatric Radiology (SPR). Radiographic examination is indicated for pediatric patients at high risk for cervical spine instability – especially those with Down syndrome.[17]

Initial Plain Film X-rays Are Not Indicated in the Following Cases

- Adult with acute uncomplicated pain (< 4 weeks duration) in any of the following
  - LBP[1] (uncomplicated definition: nontraumatic pain without neurologic deficits or indicators of potentially serious pathologies)[4]
  - Thoracic spine pain[1,4]
  - Uncomplicated neck pain[1,4]
- Adult with nontraumatic acute LBP (<4 weeks duration) AND sciatica and no red flags[1,4]
- Adult with uncomplicated subacute pain (4-12 weeks duration) in any of the following
  - LBP and no previous treatment trial[1,4]
  - Thoracic spine pain and no previous treatment trial[1,4]
  - Subacute neck pain with or without arm pain[1,4]
- Adult with persistent pain (>12 weeks) in any of the following
  - LBP and no previous treatment trial[1,4]
  - Thoracic spine pain and no previous treatment trial[1,4]
  - Persistent neck pain with or without arm pain[1,4]
- Sciatica, unless individual is age >50 or has progressive neurological deficits[4]
- Suspected lumbar disc herniation
- Suspected degenerative spondylolithesis/lateral stenosis, unless individual is age >50 or has progressive neurological deficits
- Suspected lumbar degenerative spinal stenosis, unless individual is age >50 or has progressive neurological deficits
- Adult with nonpainful and nonprogressive scoliosis
- Adult with acute neck injury and negative CCSR (Canadian Cervical Spine Rule for Radiography in Alert and Stable Trauma Patients)
- In headache complaints, vital signs (to R/O severe hypertension or fever) and testing of the cranial nerves (to R/O vascular events, space occupying lesions, etc.) should be an integral part of initial examination. Significant positive findings mandate further evaluation.[4] Without red flags or significant findings, no initial films are indicated.
- Coccyx trauma and coccydynia
- The routine use of spinal radiographs for structural and biomechanical analysis has not been substantiated to improve patient outcomes.[18] [19] The clinical evidence is insufficient to support an association between sagittal (lordosis, kyphosis) spinal curves and health outcomes including spine-related pain.[20] The utility of plain film radiography for the detection of spinal 'subluxations', or to guide the specifics of spinal manipulative therapy, is controversial.[18] "The validity of the various systems of roentgenometric analysis has not been proven and their underlying premise of bilateral symmetry within the body does not take into account natural structural anomalies".[18] Adding to this

controversy is the fact that nonspecific spinal abnormalities are common in asymptomatic patients.

- Chou et al state that "[s]trong evidence shows that routine back imaging does not improve patient outcomes, exposes patients to unnecessary harms, and increases costs".[21] Further, Andersen notes that "[a]vailable evidence indicates that immediate, routine lumbar spine imaging in patients with LBP and without features indicating a serious underlying condition, did not improve outcomes compared with usual clinical care without immediate imaging. Clinical care without immediate imaging seems to result in no increased odds of failure in identifying serious underlying conditions in patients without risk factors for these conditions. In addition to lacking clinical benefit, routine lumbar imaging is associated with radiation exposure (radiography and CT) and increased direct expenses for patients and may lead to unnecessary procedures. This evidence confirms that clinicians should refrain from routine, immediate lumbar imaging in primary care patients with nonspecific, acute or subacute LBP and no indications of underlying serious conditions."[22] Among the recommendations given for Chiropractic Management of Patients with Chronic Musculoskeletal Pain, Hawk et al, recommends avoiding the use of routing imaging, "because chronic MSK pain is often multifactorial and may not originate from a local source, imaging evidence is rarely capable of definitively identifying a pain source. However, imaging may be necessary if red flags are present and should be evaluated on a case-by-case basis after a thorough history and examination are performed."[23]

POLICY HISTORY

Date	Summary
August 2022	• Rearranged criteria under "Initial Plain Film X-rays Are Not Indicated in the Following Cases"- content was not changed • Added under plain film x-rays of the extremities ○ Evaluation of chronic hip pain – initial imaging ○ Suspected stress (insufficiency) fracture
November 2021	• Added "General Information" statement • Clarified intent of the following indication by changing the format of 'and': ○ "Adults with complicated (i.e., "red flag") LBP, thoracic pain, or neck pain **and** indicators of contraindication to SMT (relative/absolute)"
October 2020	No content changes
January 2020	No edits made to guideline in response to the review of the evidence base
July 2019	Format updated for improved readability

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Reviewed/Approved by NIA Clinical Guideline Committee

GENERAL INFORMATION

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.

National Imaging Associates, Inc.*	
Clinical guidelines **RECORD KEEPING AND DOCUMENTATION STANDARDS: CHIROPRACTIC CARE**	**Original Date: November 2015**
Physical Medicine – Clinical Decision Making	**Last Revised Date: August 2022**
Guideline Number: NIA_CG_606-02	**Implementation Date: July 2023**

Policy Statement

Recordkeeping is used to document the condition and care of the patient, avoid or defend against a malpractice claim, and support the 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 or market-specific health plan. To be covered, services must be skilled as appropriated by the following descriptions and definitions.

INDICATIONS

MEDICAL RECORD CONTENT REQUIREMENTS FOR ALL PATIENTS

GENERAL GUIDELINES

- Documentation should clearly reflect why the skills of a licensed chiropractor 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 chiropractor. The deciding factors are always whether the services are considered reasonable, effective treatments requiring the skills of a chiropractor or whether they can be safely and effectively carried out by non-skilled personnel without the supervision of a licensed chiropractor.
- 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.
- Each date of service must adequately identify the patient and include the treating chiropractor's signature and credentials. Each subsequent page in the record must also contain the patient's name or ID number.

* National Imaging Associates, Inc. (NIA) is a subsidiary of Magellan Healthcare, Inc.

- All chart entries must be dated with the month, day, and year.
- 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.
- Patient demographics including name, address, home and work telephone numbers, gender, date of birth, occupation, and marital status must be provided.
- 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.
- The reason for the encounter or referral (i.e., presenting complaint(s)).
- Each date of service must include the subjective complaint(s), objective findings, assessment, diagnosis, treatment/ancillary diagnostic studies performed, and any recommendations, instructions, or patient education.
- Services must be documented in accordance with Current Procedural Terminology (CPT®) coding criteria (e.g., location (body region), time component, etc.).
- Adverse events associated with treatment should be recorded in the patient chart.
- Copies of relevant reports and correspondence with other skilled practitioners; including, but not limited to diagnostic studies, laboratory findings, and consultations.
- Copies of reports and correspondence related to treating chiropractor's diagnostic studies, laboratory findings, and consultations, including rationale for the service or consult and findings, conclusions, and recommendations.
- Copy of discharge summary 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.
- Appropriate consent forms should be included when applicable.
- 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.
- 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.

EVALUATION

The evaluation must include:

- Documentation to support the medical need for a course of treatment through objective findings and subjective self-reporting.
- 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 individual.
- 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.

- 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.
- Baseline evaluation, including current and prior functional status (functional mobility and ADL deficits).
- Systems review consistent with the nature of the complaint(s) and relevant historical information should be included in documentation.
- 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 chiropractic best practices guidelines.
- 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]
- 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.
- Functional outcome assessment and/or standardized test results with raw scores, standardized scores, and score interpretations.
- Detailed clinical observations, as well as prognosis and rehab potential.
- Contraindications to care, with an explanation of their current management.

TREATMENT PLAN OR PLAN OF CARE (POC)

Plan of care must be individualized, goal-oriented, and aimed at restoring specific functional deficits.

Plan of care elements

- The patient's age, date of birth, and date of evaluation
- Medical history and background
- All diagnoses related to the patient's condition and contraindications to treatment as well as safety risks
- Date of onset or current exacerbation of the patient's condition
- Description of baseline functional status/limitations based on standardized testing administered or other assessment tools
- 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

- The plan of care must include goals detailing type, amount, duration, and frequency of chiropractic 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.[2]
- Visits requested must not exceed the frequency and duration supported in the plan of care
- Treatment diagnosis and specific contraindications to treatment
- Baseline/current functional status/limitations as compared to pre-episode functional status
- Patient-specific functional goals that are measurable, attainable, time-specific and sustainable. The initial plan of care for a musculoskeletal condition should not exceed 4 weeks.
- Proposed frequency and duration of treatment within a reasonable and generally predictable time period
- Specific therapeutic interventions to be provided
- Predicted level of improvement in function (prognosis)
- Specific discharge plan

Updated plan of care elements

- Time frame for current treatment period
- Total visits from start of care
- Change in objective outcome measures and standardized testing compared to baseline and/or most recent re-assessment/updated plan of care
- Measurable overall progress toward each goal including whether goal has been met or not met. Goals should be updated and modified as appropriate
- Modification of treatment interventions in order to meet goals
- Home program and self-management teaching
- Collaboration with other services/professionals
- Measurable short- and long-term functional goals that are achievable within the length of time services are requested
- Individualized targeted outcomes that are linked to functional limitations outlined in the most recent evaluation
- Intervention selections must be evidence-based and chosen to address the targeted goals
- Type of modalities and treatment interventions to be provided
- Educational plan, including home exercises, ADL modifications
- Anticipated discharge recommendations, including education of the member in a home program
- Date and signature of treating chiropractor
- Plan of care should be reviewed at intervals appropriate to the patient and in accordance with state and third-party requirements.
- The plan of care should clearly support why the skills of a licensed chiropractor are needed as opposed to discharge to self-management or non-skilled personnel without

the supervision of a licensed chiropractor. If telehealth is included, the plan of care should clearly support why the skills of a licensed chiropractor are needed as opposed to discharge to self-management or non-skilled personnel without the supervision of a licensed chiropractor.

DAILY TREATMENT NOTE

Daily notes should include:

- Standard type format (i.e., SOAP) and contain the date for return visits or follow-up
- 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.
- Assessment of patient's response or non-response to intervention and plan for subsequent treatment sessions, assessments, or updates
- Significant, unusual, or unexpected changes in clinical status

RE-EVALUATION

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:

- The patient presents with a new condition
- There is a significant or unanticipated change in symptoms or decline in functional status
- Assessment of response or non-response to treatment at a point in care when meaningful clinical change can reasonably be detected
- There is a basis for determining the need for change in the treatment plan/goals

The re-evaluation exceeds the parameters of the typical office visit and includes the following:

- Updated history
- Subjective symptoms
- Physical examination findings
- Appropriate standardized outcome tool/measurements as compared to the previous evaluation/reevaluation
- Evidence to support the need for continued skilled care
- Identify appropriate services to achieve new or existing treatment goals
- Revision in Treatment Plan, i.e., updated goals
- Correlation to meaningful change in function
- Evidence of the effectiveness of the interventions provided; progress toward goals

UTILIZATION REVIEW

Clinical Guidelines have been developed to support medically necessary treatment as part of the peer review process. Clinical documentation is evaluated when making utilization review determinations. The elements evaluated by a clinical reviewer include, but are not limited to:

- Whether treatment involves an initial trial of care or ongoing care
- Proposed services/procedures for initial trial or ongoing treatment
- Whether the reported condition was acute, sub-acute, or chronic at the onset of care
- Documentation of an exacerbation or significant flare-up, if applicable
- Whether a condition is trauma-related, insidious onset, or repetitive/overuse injuries as a result of activities of daily living
- The date of onset and mechanism of onset is specified
- A history of the current condition is documented
- An interim history is provided for recurrent episodes
- The level, intensity, and frequency of pain is recorded
- Measurable and functional treatment goals are recorded, appropriate, time-specific, and monitored
- Outcome Assessment Tools are utilized at pre-determined intervals and treatment does not continue after further meaningful change would be minimal or difficult to measure
- Treatment demonstrates functional improvement that is sustained over time and meets minimum detectable change (MDC) and/or minimum clinically important change (MCIC) requirements
- All services billed meet CPT® coding requirements; are supported by subjective complaints, objective findings, diagnoses, and treatment performed; and meet the requirements according to this organization's Clinical Guidelines
- The record demonstrates the need for skilled services as opposed to home management or unskilled services
- Patients with mild complaints and minimal functional limitations are released to a home exercise program
- Treatment has exceeded 2-3 months for the same or similar condition
- Treatment is provided on patient-directed PRN basis without a treatment plan, functional goals, or sustained improvement

LACK OF INFORMATION

Reviewers determine that claims/requests have insufficient documentation when the medical documentation submitted is inadequate to support a request for services as medically necessary, such as an initial evaluation, recent progress note and/or the most recent daily treatment notes. Incomplete notes (for example, unsigned, undated, insufficient detail) may also result in a denial for lack of sufficient information.

CONFIDENTIALITY OF RECORDS

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.

BACKGROUND

Definition

Medical Necessity

Reasonable or necessary services that require the specific training, skills, and knowledge of a chiropractor in order to diagnose, correct, or significantly improve/optimize as well as prevent deterioration or development of additional physical 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 licensed chiropractor.

- Services shall not be considered reasonable and medically necessary if they can be omitted without adversely affecting the member's condition or their quality of care.
- A service is also not considered a skilled service merely because it is furnished by a licensed chiropractor. If a service can be self-administered or safely and effectively carried out by an unskilled person, without the direct supervision of a chiropractor, then it cannot be regarded as a skilled service even though a licensed chiropractor 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 chiropractor renders the service.
- Services that include repetitive activities (exercises, skill drills) which do not require a licensed chiropractor'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.
- 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:

- **Contractual** – all covered medically necessary health care services are determined by the practitioner's contract with the payer and individual health plan benefits.

- **Scope of Practice** – medically necessary health care services are limited to the scope of practice under all applicable state and national health care boards.
- **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.
- **Patient Safety** – all health care services must be delivered in the safest possible manner.
- **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.
- **Setting** – all health care services must be delivered in the least intensive setting.
- **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.
- **Clinical Guidelines**– health care services are considered medically necessary if they meet all of the Clinical Guidelines of this organization.

Medical History: **Applicable to all Network Providers**

The Medical History includes all of the following:

- The History of Present Illness (HPI) includes the location, quality, severity, duration, timing, context, modifying factors that are associated with the signs and symptoms
- A Review of Systems (ROS) – 13 systems (musculoskeletal/neurological, etc.) and constitutional symptoms. Should also address communication/language ability, affect, cognition, orientation, consciousness
- Past Medical, Family and Social History (PFSH) that includes the patient's diet, medications, allergies, hospitalizations, surgeries, illness or injury, the family health status, deaths, problem-related diseases, and
- The patient's social status that includes marital status, living conditions, education/occupation, alcohol/drug use, sexual history

Physical Examination (PE): **Applicable to Chiropractors (CHIRO)** Examination of the body areas that includes the head, neck, chest, abdomen, back, and extremities, and the organ systems (11), constitutional, eyes, ENT, CV, GI, GU, musculoskeletal, skin, neurological, psychiatric, lymphatic, immunological, and hematological.

New Patient:

The patient has not been seen at any time by any practitioner within the same group practice, for any purpose, within the last 3 years.

Starting on January 1st, 2021, providers may select the level of office and outpatient Evaluation and Management (E/M) services based on either Time or Medical Decision Making.

Selecting an E&M Code Based on Medical Decision Making[3]

A new medical decision-making table was created in 2021 to provide guidelines for E/M code level selection. Documentation should support the E/M service chosen.[3]

The medical decision-making elements associated with codes 99202-99215 will consist of three components:

1) Problem: The number and complexity of problems addressed
2) Data: Amount and/or complexity of data to be reviewed and analyzed
3) Risk: Risk of complications and or morbidity or mortality of patient management.

In order to select a level of an E/M service, two of the three elements of medical decision making must be met or exceeded.

Using Time to Select an E&M Code

According to the AMA 2022 CPT® codebook,[4] physician or other qualified healthcare professional time includes the following activities:

- preparing to see the patient (e.g., review of tests)
- obtaining and/or reviewing separately obtained history
- performing a medically appropriate examination and/or evaluation
- counseling and educating the patient/family/caregiver
- ordering medications, tests, or procedures
- referring and communicating with other health care professionals (when not separately reported)
- documenting clinical information in the electronic or other health record
- independently interpreting results (not separately reported) and communicating results to the patient/family/caregiver
- care coordination (not separately reported)

Code	Time range	Code	Time range
99202	15-29 minutes	99212	10-19 minutes
99203	30-44 minutes	99213	20-29 minutes
99204	45-59 minutes	99214	30-39 minutes
99205	60-74 minutes	99215	40-54 minutes

When using time to select an E&M code, a medically appropriate history and examination must still be documented.[5]

POLICY HISTORY

Date	Summary
August 2022	• No content changes • References Updated
December 2021	• Original Record Keeping and Documentation Standards guideline split into two new separate guidelines to clearly delineate differences between Chiropractic Care and Speech/PT/OT. The two new guidelines are titled as follows: o Record Keeping and Documentation Standards: Chiropractic Care o Record Keeping and Documentation Standards: Physical Medicine • Added section on selecting the level of office and outpatient Evaluation and Management (E/M) services based on either Time or Medical Decision Making • Removed PT/OT/Speech indications and coding information from Chiropractic Care guideline • Added "General Information" statement
October 2020	• Added teletherapy in the policy statement • Added start of care be listed on progress note requirements • Moved CPT codes to background • Added indication of home program compliance for max benefit of therapy as part of updated POC • Added accommodative language to be inclusive of chiropractic care in medical necessity definition • Added support for excessive frequency/duration requests being in accordance with accepted standard of practice • Added parenthetical evaluation section to clarify that treatment should not focus on return to activities beyond normal daily living (sport/recreation/work) • Added that visits requested must not exceed the frequency and duration supported in the plan of care • Added qualifier for proof of skilled treatment for requested frequencies regardless of level of severity of delay
January 2020	• No edits made to guideline in response to the review of the evidence base
July 2019	• Definitions moved to the background so that relevant information is more readily available

	• Organization of material into subcategories as well as formatting CPT code tables and deleting repetitive information for consistency and readability • Clarification and grammar edits to provide greater detail • Additional caveats for medical necessity/non-skilled interventions included as greater support for lack of skill denials • Updated references

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ADDITIONAL RESOURCES

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Reviewed/Approved by NIA Clinical Guideline Committee

GENERAL INFORMATION

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.

National Imaging Associates, Inc.*	
Clinical Guidelines **ACTIVE PROCEDURES IN PHYSICAL MEDICINE**	**Original Date: November 2015**
Physical Medicine – Clinical Decision Making	**Last Revised Date: September 2022**
Guideline Number: NIA_CG_608	**Implementation Date: July 2023**

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]

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.

Scope
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.

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]

Timing of Introduction
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]

* National Imaging Associates, Inc. (NIA) is a subsidiary of Magellan Healthcare, Inc.

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.

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]

Documentation Requirements

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]

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]

Billing Units

This organization 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

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

CPT Code Definitions, Examples, and Requirements

97110 - Therapeutic Exercise

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.

Parameters for Use:

The following requirements must be documented in the medical record to support and justify the use of all therapeutic procedures/exercises:

- Evidence to support medical necessity
- 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
- Detailed description of active care services including:
    - What exercise(s) were provided
    - What area and muscle groups the exercise(s) were provided to
    - Amount and type of resistance, number of repetitions and sets, and time component
- Evidence to support the need for skilled services completed by a licensed professional in direct contact with one patient

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.

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.

This documentation must:

- 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
- Provide evidence of functional improvement as a result of the increased muscle strength
- Clearly state the skilled service being provided
- Provide evidence for why the skills of a physical medicine provider/practitioner are needed beyond progressing weights and repetitions
- Provide evidence for why the skills of a physical medicine provider/practitioner are needed beyond a few visits to establish a program
- Show that the therapeutic exercise is part of a comprehensive rehab program
- Include a plan of care driven by impairments, not the intervention itself
- Clearly demonstrate that increasing muscle strength is the treatment of choice (e.g., strength building may be detrimental in an individual with movement restrictions).

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).

Support for this service

- 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.

- 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.

- 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.

- 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.

- 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.

97112 - Neuromuscular re-education[19]
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:

- 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.
- The patient has nerve palsy, such as peroneal nerve injury causing foot drop.
- 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.
- The patient has muscle compensations requiring targeted exercise to produce stable, coordinated movements during functional tasks.[20]
- 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]

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.

Support for this service

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

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.

97113 - Aquatic Therapy[23]

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.

Support for this Service

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.

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.

97116 - Gait Training

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.

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.

Support for this Service

The provider should consider the contextual factors that affect a person’s ability to participate in meaningful ADLs. Gait training and ambulation interventions should directly address

functional mobility.[30] 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.

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.

97760 - Orthotics Management and Training
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.

Explanation
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.

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.

Support for this Service
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.

Documentation must also support why the skills of a licensed professional are needed for the training in care and use of the orthotic.

97761 - Prosthetic Training
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.

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.

97763 - Checkout for Orthotic/Prosthetic Use, Established Patient
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.

Support for this Service
Documentation must clearly support the skilled need of a licensed professional for the adjustments.

97530 - Therapeutic Activities
Definition
This code includes the use of dynamic activities in teaching and training the patient to improve functional performance in a progressive manner.

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.

Support for this Service
Documentation must support the need for skilled services by a licensed professional in direct contact with one patient.

In order for therapeutic activities to be covered, all the following requirements must be met:

- The patient has a condition for which therapeutic activities can reasonably be expected to restore or improve function
- 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
- 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

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.

97129 - Cognitive Skills Development
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.

Examples
Individuals with inherited learning disabilities, individuals who have lost cognitive skills as a result of illness or brain injury

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

97533 - Sensory Integration
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.

Examples
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.

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.

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

Support for this Service
Sensory integration therapy is usually provided by occupational and physical therapists who are certified in sensory integration therapy.

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

97535 -Self-care/Home Management Training
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.

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.

Support for this Service
Documentation must support the need for skilled services by a licensed professional in direct contact with one patient. 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.

97542 -Wheelchair Management and Training
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).

Support for this Service
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.

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.

The documentation must clearly support that the services rendered required the skills and expertise of a licensed therapist.

97537 -Community Work Reintegration – <u>typically not a covered service</u>
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.

Example
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.

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.

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.

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.

97545 -Work Hardening/Conditioning – **typically not a covered service** – initial 2 hours, use 97546 for each additional hour and use in conjunction with 97545

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.

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.

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.

BACKGROUND
A qualified health care provider is an individual who by education, training, and licensure/regulation performs a professional service within his/her scope of practice and reports a professional service. These providers are distinct from 'clinical staff' (e.g., physical therapy aide or speech language assistant). A clinical staff member is a person who works under the supervision of a qualified health care provider and who is allowed by law or regulation to perform or assist in the performance of a specified professional service. Examples of qualified health care providers for the purpose of this policy include chiropractors, physical therapists, occupational therapists, physician assistants, speech therapists, physical therapist assistants, and occupational therapy assistants.

Skilled care services are not required to effect improvement or restoration of function when a patient suffers a transient and easily reversible loss or reduction of function, which could reasonably be expected to improve spontaneously as the patient gradually resumes normal activities. Skilled care services furnished in such situations are not considered reasonable and necessary for the treatment of the individual's illness or injury.

Definition
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:

- Functional assessment from standardized and validated outcomes instruments; or
- 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.

POLICY HISTORY

Date	Summary
September 2022	• References added • Billing Units: Added "≥" to billing unit descriptions • Therapeutic exercise: Changed "therapist" to "physical medicine provider/practitioner" • Revised CPT code for Cognitive Skills Development • Added information to identify difference between sensory integration and neuromuscular re-education • Minor editorial changes
December 2021	• Added "General Information" statement • Updated billing units according to CMS LCA • Added VBRT under neuromuscular re-education • Clarified support for service for 97761-Prosthetic Training • Removed Code 97760 cannot be reported with gait training (97116)
October 2020	No content changes
December 2019	Minor editorial edits only
July 2019	• Updated references (pulled any older than 10 years and provided updated reference if necessary). • Provided further definition for use of neuromuscular re-education.

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Reviewed/Approved by NIA Clinical Guideline Committee

GENERAL INFORMATION

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.

National Imaging Associates, Inc.*	
Clinical guidelines **DURABLE MEDICAL EQUIPMENT**	**Original Date: April 2016**
Physical Medicine – Clinical Decision Making	**Last Revised Date: August 2022**
Guideline Number: NIA_CG_609	**Implementation Date: July 2023**

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.

Scope
This policy applies 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.

Medical Necessity
Durable Medical Equipment and services are medically necessary when ALL of the following criteria are met:

- The equipment is expected to provide improvement in specific measurable functional deficits related to a documented illness or injury
- The DME is provided by a health care professional
- The equipment has significant medical uses
- Lesser or alternative options have been ruled out
- The clinical records clearly establish the medical need for the DME

Clinical documentation must include the following elements:

- A diagnosis that justifies the equipment or supply being requested
- A treatment plan (anticipated start and end date) for the training and/or use of the DME
- Measurable functional deficit(s)
- Expected outcomes and benefit related to a measurable functional deficit
- 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
- Evidence of a trial of conservative services that failed to improve a measurable functional deficit unless contraindicated
- When appropriate, evidence of an in-office trial use that provided improvement in a measurable functional deficit

* National Imaging Associates, Inc. (NIA) is a subsidiary of Magellan Healthcare, Inc.

- When appropriate, evidence of home or vehicle assessment to ensure equipment could be utilized in the home or vehicle
- Evidence of prior equipment for a similar purpose, and reasons that equipment no longer meets current needs
- If an insurance plan does not cover the specific DME, then any visit associated with instruction on the DME would not be covered

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BACKGROUND:

Definition

- DME is any equipment that provides therapeutic benefits to an individual for certain conditions and/or illnesses defined below.
- DME consist of items which:
    - Are used to treat a defined illness or injury
    - Are useful to a person with an illness or injury
    - Are reusable and durable enough for repeated use
    - Are appropriate for use outside of a medical setting such as home, at school, or work
- DME includes but is not limited to:
    - Back, knee, and ankle supports/braces
    - Cervical collars
    - Foot orthotics
    - Electrical stimulation units and supplies
    - Traction devices
    - Hospital beds
    - Equipment to aid with bathing, toileting, and dressing
    - Splints/slings
    - Equipment to aid with seating and positioning
    - Wheelchairs and assistive devices for gait
- 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]

POLICY HISTORY

Date	Summary
August 2022	• References updated • Minor editorial changes
December 2021	• Added “General Information” statement • Clarified Policy Statement • Expanded list of possible DME examples
October 2020	• Changes made to broaden the scope of the guideline and remove specific types of DME. Will utilize other guidelines for specific DME items.

	• Added documentation to show lesser or alternative equipment was not appropriate • Added documentation of home or vehicle assessment to ensure equipment could be used as intended • Expanded list of possible DME examples
January 2020	No edits made to guideline in response to the review of the evidence base
July 2019	• Addition to assistive device section: spinal cord injury, muscular dystrophy, wheelchair user population, spinal muscular atrophy, brain injury, cerebral palsy, Rett Syndrome, and ASD. • Completed pulling of older references (10+ years) and replaced references that were appropriate to this guideline. • Moved definition section to background.

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Reviewed/Approved by NIA Clinical Guideline Committee

GENERAL INFORMATION

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.

National Imaging Associates, Inc.*	
Clinical guidelines **EXPERIMENTAL, UNPROVEN, OR INVESTIGATIONAL SERVICES**	**Original Date: November 2015**
Physical Medicine – Clinical Decision Making	**Last Revised Date: August 2022**
Guideline Number: NIA_CG_601	**Implementation Date: July 2023**

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.

Purpose
To provide a listing of procedures considered experimental, investigational, or unproven services by any physical medicine practitioner, including chiropractors, physical therapists, occupational therapists, and speech language pathologists.

Coverage
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.

Definition
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.

* National Imaging Associates, Inc. (NIA) is a subsidiary of Magellan Healthcare, Inc.

- 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.

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.

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]
- 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 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

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]

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.

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]

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.

The appropriateness and effectiveness of chiropractic manipulation as a preventive or maintenance therapy has not been established by clinical research and is not covered.

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.

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.

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.

Procedure

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

- **Exclusions/Limitations (not limited to)**

Refer to enrollee's Certificate of Coverage or Summary Plan Description.

- **Removal of a service from the Experimental and Investigations Policy**

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:

- Safety – Is the potential benefit superior to the potential harm?
- Health Outcomes – Is there evidence the service will provide, at minimum, equal outcomes and at best, superior outcomes to currently available services?
- Patient Management – Will the service improve clinical decision making?
- Clinical Performance – Is the reliability as well as predictive value of the service equal or superior to the current "gold standard" for such services?
- Cost-effectiveness – Is the service equal to or lower cost than currently utilized services for similar diagnosis and treatment?

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.

If the service appears to be safe and cost-effective, this organization 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.

POLICY HISTORY

Date	Summary
August 2022	• Removed "Maintenance Care" from the list of E & I services • References updated
December 2021	• Added "General Information" statement • Reordered (in alphabetical order) the list of experimental and investigational services • Added Blood Flow Resistance Training to list of E&I services
August 2020	No content changes
January 2020	No content changes following review of the evidence base. Minor copyediting changes.
July 2019	Older references updated or omitted as appropriate.

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Reviewed/Approved by NIA Clinical Guideline Committee

GENERAL INFORMATION

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.

National Imaging Associates, Inc.	
Clinical guidelines **MEASURABLE PROGRESSIVE IMPROVEMENT**	**Original Date: November 2015**
Physical Medicine – Clinical Decision Making	**Last Revised Date: October 2022**
Guideline Number: NIA_CG_605	**Implementation Date: July 2023**

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.

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.”

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, this organization

has concluded all practitioner records must evaluate and document whether treatment is resulting in progressive and sustained improvement.

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 functional 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: <u>Global Rating of Change (GRoC)</u>
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.

BACKGROUND

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 Functional Goals
Clearly defined goals of treatment that allow measurement of the amount and/or degree of meaningful change 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.

POLICY HISTORY

Date	Summary
October 2022	• ABC - added MCID for vestibular disorders • BBS – Added MCID for subacute stroke

	• Functional Gait Assessment – added MCID for vestibular disorders • Gait Speed for Adults – Added MCID for vestibular disorders • Removed "older" from "Gait Speed for Older Adults" • KOOS Score – Added MCID scores • NPRS – added MCID for spinal cord injuries • Pain Disability Index – added "in individuals with chronic back pain" • PSFS – Added MDC for older adults • Added Simple Should Test (SST) and MCID scores • TUG Added MDC for THA, and MCID for post DDD surgery • VAS added MCID score for hand surgery • PDI added "in individuals with chronic back pain"

December 2021	• Added "General Information" statement
	• Under 6MWT
	  ○ Removed MDC calculated from SEM of 58.21 m (190.98 ft)
	  ○ For older people with limited mobility, changed "SEM" to "SMC"
	  ○ Added either hip OA or knee OA that later received a total joint replacement
	• Updated MDCs for Activity-Specific Balance Confidence Scale (ABC)
	• Added Bruininks-Oseretsky Test of Motor Proficiency, 2nd Edition (BOT-2)
	• Updated QuickDASH MCID
	• Updated Falls Self Efficacy Scale/Falls Efficacy Scale-International (FES-I) MDC values
	• Added following arthroscopic subacromial decompression MCIC to FAB-Q
	• Added heart failure, joint pain, and fracture (MDC and MCID) to Gait Speed for Older Adults
	• Added Gross Motor Function Measure-66 (GMFM-66)
	• Simplified MDCs for KOOS
	• Updated MCID for LEFS
	• Updated MDC of Neck Disability Index
	• Added Peabody Developmental Motor Scales-2nd Edition (PDMS-2)
	• Added Pediatric Balance Scale
	• Added MCID in individuals with knee dysfunction, cervical radiculopathy, or chronic low back pain to PSFS

	• Added Alzheimer disease, Parkinson disease, and chronic stroke MCDs to TUG
October 2020	Added MCID numbers for WOMAC

January 2020	• Under the sub-head Acceptable Thresholds of Measurable Improvement Activity-Specific Balance Confidence Scale was added:
	  ○ Activities of Daily Living Scale of the Knee Outcome Survey
	  ▪ Activity-Specific Balance Confidence Scale (ABC)
	  ○ Disability of Arm, Shoulder, and Hand (DASH, qDASH)
	  ▪ DASH MCID = 11-15 points
	  ▪ QuickDASH MCID = 11-15 points
	  ○ Falls Self Efficacy Scale
	  ○ MDC = 8.2 points
	• Foot and Ankle Ability Measures (FAAM)
	  ○ ADL subscale MCID = 8 points
	  ○ Sport subscale MCID = 9 points
	• Fear Avoidance Belief Questionnaire (FAB-Q)
	• Global Rating of Change (GRoOC)
	  ○ MDC .45 points on 11 point scale
	  ○ MCIC 2 points on 11 point scale
	• Knee Injury and Osteoarthritis Outcome Score (KOOS)
	  ○ Extension of the WOMAC assessment
	  ○ Pain subscale MDC = 22 points
	  ○ Stiffness subscale MDC = 29 points
	  ○ Physical Functional subscale MDC = 13 points
	  ○ Other subscale MDC: 14 points
	• Knee Outcome Survey
	  ○ MDC = 9 points
	  ○ MCID = 7 points
	• Lysholm Knee Rating System
	  ○ MDC = 10 points
	• Oswestry Disability Index: The Minimal Important Change is 10 points or a 20% improvement (Previously 30% improvement)

July 2019	• Definitions moved to the background • Minor grammar and format edits

	• Check validity of references with one addition – some references are from older sources however the information is still relevant

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Reviewed/Approved by NIA Clinical Guideline Committee

GENERAL INFORMATION

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.

National Imaging Associates, Inc.*	
Clinical guidelines **PASSIVE TREATMENT**	**Original Date: November 2015**
Physical Medicine – Clinical Decision Making	**Last Revised Date: August 2022**
Guideline Number: NIA_CG_604	**Implementation Date: July 2023**

Policy Statement

This organization 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 dictated by the health plan.

Definitions

Modality

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

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

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

* National Imaging Associates, Inc. (NIA) is a subsidiary of Magellan Healthcare, Inc.

Procedure

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

The following is a list of procedures and modalities considered to be passive treatment:

- Thermal and light therapy – Hot/cold (97010), diathermy (97024), microwave (97020), infrared (97026), ultraviolet (97028), ultrasound (US) (97035), paraffin bath (97018), and whirlpool (97022).

- Electrical therapy – High volt, low volt, interferential current, transcutaneous electrical nerve stimulation (TENS) (97014 and 97032).

- Mechanical – mechanically assisted and often a sustained pull of the spine or limb, such as traction (97012).

- 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.

Appropriate Use of Passive Treatment

- 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.

- Passive treatment is considered to be clinically appropriate and/or necessary in the conservative management of neuromusculoskeletal conditions when:
    - There are no contraindications to the intervention
    - Self-administration is implausible or places the patient at risk of harm
    - Used primarily during the initial period of an episode of treatment
    - Used to support an active care approach (i.e., therapeutic exercise)
    - Used for a particular condition for which there is an evidence-basis of significant benefit

- Passive treatment is considered NOT to be clinically appropriate and/or necessary when:
    - Patient safety is jeopardized by the application of the modality
    - The treatment can safely and effectively be administered by the patient or another individual
    - Used during a course of treatment, which continues beyond the initial period

- Used as the primary or sole therapy
- Greater than one passive treatment is used involving the same body region(s)
- Used largely for the comfort and convenience of the patient
- Used as part of the routine office protocol

Exclusions

- 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 for the following:

    - 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.

BACKGROUND

The preponderance of evidence appears to support either a lack of efficacy or insufficient data to make a judgment on benefit for the modalities evaluated. When a positive outcome was described, the reported treatment effects were modest. Similarly, the duration of treatment effectiveness was typically reported as short (2 weeks to 2 months). Most international guidelines recommend these interventions should only be used reservedly based upon individual circumstances, and not as a principal component of a treatment regime.

The use of passive modalities in the treatment of neuromusculoskeletal conditions presents the inherent risk of promoting passive dependence. It is the responsibility of the treating practitioner to judiciously apply passive modalities and encourage active patient participation in the treatment plan. Passive treatment is generally viewed as appropriate when used for a short period of time and in conjunction with active care.

Low Back Pain and Passive Interventions

A review on non-pharmacological therapies for acute and chronic LBP by the American Pain Society and the American College of Physicians concluded that therapies with good evidence of moderate efficacy for chronic or sub-acute LBP are cognitive-behavioral therapy, exercise, spinal manipulation, and inter-disciplinary rehabilitation.[1]

Studies suggest that spinal manipulation may provide modest pain relief and improved function for patients with acute low back pain (pain that has come on within the last four weeks) or chronic (longer-term) low back pain and generally appears to be safe.[2] A meta-analysis of 26 RCTs report statistically significant improvement in both pain and function for patients with LBP who received SMT with only a reporting of minor transient adverse events, including muscle

stiffness, pain, and headache.[3] Clinical Guidelines from The North American Spine Society (2020) recommend, based on good evidence, that "[f]or patients with acute low back pain, spinal manipulative therapy (SMT) results in similar outcomes to no treatment, medication or modalities. Periodically, short-term improvement is statistically better, but clinical significance is uncertain."[4]

Surface electrical muscle stimulators (direct or alternating current, not high-voltage galvanic current) are considered experimental and investigational for the management of idiopathic scoliosis because there is inadequate evidence of its effectiveness and safety in the peer-reviewed published medical literature.[5]

For patients with low back pain, the use of transcutaneous electrical nerve stimulation (TENS) is not a recommended intervention.[6,7] Green et al found that transcutaneous electrical nerve stimulation (TENS) offers no significant benefit for chronic low back pain particularly concerning multiple disability and quality of life measures, but it does offer a small benefit in pain reduction compared with sham treatment. Their study suggests that TENS may be a useful adjunct in select patients for pain control to reduce the need for medication.[8] Likewise, a 2017 study of 127 patients with LPB split into five different comparison groups, including TENS, or a control concluded that the "TENS currents and high voltage [electrical stimulation] were helpful, but not as effective. The use of diadynamic currents appears to be useless."[9]

Guidelines on treatment of low back pain from the National Collaborating Centre for Primary Care found insufficient evidence for the use of interferential stimulation in LBP and recommended against its use for that indication.[10,11]

A Cochrane review of 32 RCTs involving 2762 participants found that "traction, either alone or in combination with other treatments, has little or no impact on pain intensity, functional status, global improvement and return to work among people with LBP. There is only limited-quality evidence from studies with small sample sizes and moderate to high risk of bias. The effects shown by these studies are small and are not clinically relevant."[12] Similarly, the study by Alrwaily and colleagues found that the use of traction in the treatment of low back pain is inconclusive,[13] and Chou et al (2016) found that traction has little or no impact on pain intensity, functional status, or global improvement.[14]

No high-quality evidence was found to support the use of ultrasound for improving pain or quality of life in patients with non-specific chronic LBP. There is some evidence that therapeutic ultrasound has a small effect on improving low-back function in the short term, but this benefit is unlikely to be clinically important. Evidence from comparisons between other treatments and therapeutic ultrasound for chronic LBP were indeterminate and generally of low quality.[15] The current evidence does not support the use of therapeutic ultrasound in the management of chronic LBP.[16]
The Cochrane Back and Neck Group reported little confidence that massage is an effective treatment for LBP. Acute, sub-acute, and chronic LBP had improvements in pain outcomes with

massage only in the short-term follow-up. Functional improvement was observed in participants with sub-acute and chronic LBP when compared with inactive controls, but only for the short-term follow-up.[17]

A number of nonpharmacological, noninvasive treatments for low back pain are associated with small to moderate, primarily short-term effects on pain versus placebo, sham, wait list, or no treatment. Effects on function are generally smaller than effects on pain. More research is needed to understand optimal selection of treatments, effective combinations, and sequencing of treatments, and effectiveness of treatments for radicular low back pain.[18] There is insufficient data to draw firm conclusion on the clinical effect of back schools, low-level laser therapy, patient education, massage, traction, superficial heat/cold, and lumbar supports for chronic low back pain.[19] Clinical Guidelines from The North American Spine Society (2020) recommend, based on good evidence, that "[i]n patients with subacute or chronic low back pain, traction is not recommended to provide clinically significant improvements in pain or function." An additional recommendation, based on fair evidence, states "[u]ltrasound does not improve functional outcomes in patients with chronic low back pain."[4]

Neck Pain and Passive Interventions

No trials at low risk of bias support the use of traction, stretching, or ultrasound therapy for chronic neck pain. However, Yang et al found that intermittent cervical traction (ICT) may have short-term pain relief effects, but generally the information regarding ICT is inconclusive.[20] Likewise, a 2018 systematic review reported "some support to the use of the mechanical and manual traction for CR [cervical radiculopathy] in addition to other physical therapy procedures for pain reduction, but yielding lesser effects on function/disability", but the reviewers note a lack of homogeneity in diagnostic criteria among the included studies.[21,22]

Low quality evidence suggests clinically important long-term improvements in neck pain, function/disability, and global perceived effect, when manual therapy and exercise are compared to no treatment. High quality evidence suggests greater short-term pain relief than exercise alone,[23] but no long-term differences across multiple outcomes for (sub) acute/chronic neck pain with or without cervicogenic headache. Moderate quality evidence supports this treatment combination for pain reduction and improved quality of life, over manual therapy alone for chronic neck pain and suggests greater short-term pain reduction when compared to traditional care for acute whiplash. Evidence regarding radiculopathy was sparse.[24]

Coulter et al found that there is low to moderate quality evidence that various types of manipulation and/or mobilization will reduce pain and improve function for chronic nonspecific neck pain compared to other interventions, however multimodal approaches have the greatest potential impact.[25] Likewise, Díaz-Pulido et al report that manual therapy resulted in significantly better improvement in patients with chronic neck pain at post-intervention and at 6-month follow-up as compared to patients undergoing TENS therapy.[26]

Both stretching exercises and manual therapy considerably decreased neck pain and disability in women with non-specific neck pain. The difference in effectiveness between the two treatments was minor. Low-cost stretching exercises can be recommended in the first instance, as an appropriate therapy intervention to relieve pain, at least in the short-term.[27]

Combining different forms of manual therapy with exercise is better than manual therapy or exercise alone.[28]

Manual trigger point treatment of head and neck muscles may reduce frequency, intensity, and duration of attacks in tension-type headaches and migraine headaches, but the quality of evidence according to GRADE approach was very low for the presence of few studies, high risk of bias, and imprecision of results.[29]

There is a linear dose-response relationship between SMT visits and days with cervicogenic headache (CGH). For the highest and most effective dose of 18 SMT visits, CGH days were reduced by half and about 3 more days per month than for the light-massage control.[30]

For the treatment of the diagnostic label Non-Specific Neck Pain (NP), strong evidence of efficacy was only found for multimodal care (manipulation/mobilization and supervised exercises).[31] A prospective double-blind randomized controlled trial examining the effects of multimodal care on patients with NP, plus/minus addition of neck-specific aerobic exercise, showed statistically significant reduction in both NP and cervicogenic headache.[32]

Interferential current (IFC) therapy is effective in the treatment of chronic neck pain patients. However, the results of clinical trials, to date, have been conflicting regarding whether IFC has additional benefit or superiority over neck stabilization exercises. Additional research is required.[33,34]

In regards to chronic mechanical neck pain, stabilization exercises with or without connective tissue massage (CTM) might be a useful treatment, however stabilization exercises with CTM are superior in improving pain intensity at night, pressure pain threshold, state anxiety, and mental health compared to stabilization exercises alone.[35]

Thrust manipulation and non-thrust mobilization was less effective when performed alone than when combined with therapeutic exercises for mechanical neck pain with or without headaches.

Cervical traction has not been shown to be effective in the treatment of neck pain.[36] A meta-analysis of randomized controlled trials showed that the use of intermittent cervical traction for treating neck pain did not differ significantly from a placebo during the follow-up period after treatment.[20]

TMJ and Passive Interventions

No high-quality evidence was found, indicating that there is great uncertainty about the effectiveness of exercise and manual therapy for treatment of temporomandibular joint dysfunction. A 2022 systematic review compared the efficacy of nonpharmacological therapies (such as acupuncture, physiotherapy, low-level laser, and massage) for painful temporo-mandibular disorders and found "the overall quality of evidence of nonpharmacological treatments was low showing that there is lack of certainty about these therapies as options for the pain-relieving in TMJD". Laser therapy, and physiotherapy were found to be "potentially useful interventions" lasting effects could not be determined due to the lack of consistency and short-term follow-up in included studies.[37]

Shoulder Pain and Passive Interventions
For adults with nonspecific shoulder pain of variable duration, cervicothoracic spinal manipulation and mobilization, in addition to usual care, may improve self-perceived recovery compared to usual care alone. For adults with subacromial impingement syndrome of variable duration, neck mobilization in addition to a multimodal shoulder program of care, provides no added benefit.[38]

For patients with rotator cuff tendinopathy, based on low to moderate-quality evidence, manual therapy may decrease pain; however, it is unclear whether it can improve function.[39] One meta-analysis notes, "When combined with exercise, manual therapy was superior to exercise alone, but only at the shortest follow-up".[40]

There was little evidence that active therapeutic ultrasound is more effective than placebo ultrasound for treating people with pain or a range of musculoskeletal injuries or for promoting soft tissue healing.[41,42] A Cochrane Database Review of the use of ultrasound with patients suffering from rotator cuff disease notes no difference between the US and control grounds in long-term follow-up (nine months).[43] A double-blind study by Analan et al showed that ultrasound does not provide additional benefit to the physiotherapy treatment regimen concerning pain, function, and isokinetic shoulder rotator cuff strength.[15] Additionally, a systematic review and meta-analysis that evaluated the clinical outcomes of ultrasound deep heat therapy in patients with adhesive capsulitis reported improvement in pain when accompanied by co-interventions. However, when compared to other treatment modalities together with exercise or physiotherapy, no additional benefits were found.

Deep tissue friction massage has been shown to be beneficial in improving function and range of motion in supraspinatus tendinitis patients.[44]

Hip Pain and Passive Interventions "
The best available evidence indicates that exercise therapy (whether land-based or water-based) is more effective than minimal intervention in managing pain associated with hip osteoarthritis (OA) in the short term. Larger high-quality randomized controlled trials (RCT) are needed to establish the effectiveness of exercise and manual therapies in the medium and long term.[45-47]

Knee Pain and Passive Interventions
Chaves found that deep friction massage (DFM) significantly decreased pain intensity over time in individuals with patellar tendinopathy, regardless of the pressure used. The authors note, "DFM induces an immediate reduction in pain intensity upon palpation,… Notwithstanding, the reader should take into account the small sample size and the caution needed in the results' interpretation."[48]

Studies using therapeutic ultrasound for the treatment or management of knee pain have had conflicting results to date. In a meta-analysis of the use of ultrasound (US) therapy in treating myofascial pain syndrome (MPS), the researchers conclude, "Owing to the high risk of bias and the across-trial heterogeneity of the studies, the current evidence is not clear enough to support US as an effective method to treat MPS."[49] Another meta-analysis notes a statistically significant decrease in pain for patients with knee osteoarthritis undergoing therapeutic ultrasound therapy as compared to the individuals in a sham ultrasound control group.[50]

For patients with knee osteoarthritis, the use of transcutaneous electrical nerve stimulation (TENS) may provide pain relief; however, the evidence is limited.[51-53]

Ankle Pain and Passive Interventions
For adults with grade I-II ankle sprains of variable duration, lower extremity mobilization, in addition to home exercise and advice, provides greater short-term improvements in activities and function over home exercise and advice alone.[38]

For patients with acute exercise-induced Achilles tendinopathy, low level laser therapy may be helpful in reducing inflammation and pain.[54]

In patients with Achilles tendinopathy of < 3 months, the use of iontophoresis was shown to help with pain. However, the control group still demonstrated improvements with the use of a comprehensive rehabilitation program.[55]

Chronic Pain and Passive Interventions
"Passive therapy (those treatment modalities that do not require energy expenditure on the part of the patient) can provide short-term relief during chronic pain flare-ups and is directed at controlling symptoms such as pain, inflammation, and swelling. Passive therapies may be useful over the short term but have limited benefit for chronic pain conditions overall."[56]

Electrical Stimulation and Laser Therapy
In a systematic review and meta-analysis, Fuentes analyzed the available information regarding the efficacy of interferential therapy in the management of musculoskeletal pain. Interferential current alone was not significantly better than placebo or other therapy at discharge or follow-up.[57] In addition, a systematic review and meta-analysis analyzed the efficacy of interferential current in alleviating musculoskeletal pain. It was reported that interferential current alone

demonstrated a significant pain-relieving effect compared to a placebo and that there was "no significant difference when added to standard treatment compared with placebo plus standard treatment or standard treatment alone."

There is a paucity of evidence in the peer-reviewed literature regarding the effectiveness of high-voltage, pulsed current treatments in humans as a means of controlling edema and post-traumatic pain; thus, a clear evidence base has not yet been established.

Scientific evidence in the peer review literature is lacking regarding the use, safety, improvement, or effectiveness on health outcomes for light emitting diode (infrared) therapy.

In a systematic review and meta-analysis, Song, et al (2018) found that high intensity laser therapy is able to significantly reduce pain and disability in patients with back and neck pain.[58]

Documentation Requirements
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.

Applicable contraindications for passive modalities (e.g., ultrasound therapy) should be considered.

POLICY HISTORY

Date	Summary
August 2022	• No changes to indications • Additional information added to the Background section for Low Back Pain and Passive Interventions, TMJ and Passive Interventions, Shoulder Pain and Passive Interventions, and Electrical Stimulation and Laser Therapy • Updated references
December 2021	• Added "General Information" statement • Expansion of the Background section to strengthen the presentation of the evidence-base in support of the indications. • Minor copyediting changes
October 2020	• Modified the definition of "Modality" to include manual/massage therapy

	• Modified “Appropriate Use of Passive Treatment” by clarifying when passive modalities may be utilized • Modified “Appropriate Use of Passive Treatment” by clarifying passive modalities as not clinically appropriate and/or necessary by adding effectively be performed by the patient or another individual • Modified the “Definitions” section to better distinguish between modalities and passive treatment
January 2020	• No changes to indications • Expansion of the Background section to strengthen the presentation of the evidence-base in support of the indications. • Minor copyediting changes
July 2019	• Older references updated or omitted as appropriate. • Background information expanded to reflect scope of current evidence base.

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ADDITIONAL RESOURCES

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Reviewed/Approved by NIA Clinical Guideline Committee

GENERAL INFORMATION

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.