

2025 Evolent Clinical Guidelines for Medical Necessity Review - HMSA

PHYSICAL MEDICINE GUIDELINES Effective July 1, 2025 – June 30, 2026



Guidelines for Clinical Review Determination

Preamble

Evolent 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 Evolent 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, and other specialty groups. Evolent's guidelines are reviewed yearly and modified when necessary following a literature search of pertinent and established clinical guidelines and accepted diagnostic imaging practices.

All inquiries should be directed to:

Evolent Specialty Services, Inc.

c/o Privacy

1812 N. Moore St, Suite 1705, Arlington, VA 22209

Fax 800-830-1762 / Privacy@Evolent.com



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Experimental Unproven Investigational Services Measurable Progressive Improvement Passive Treatment



HMSA Clinical Guideline 1506 for Outpatient Habilitative Physical and Occupational Therapy

Administered by Evolent

Guideline Number:							
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STATEMENT

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.

Purpose

This guideline describes the documentation requirements for an episode of care for outpatient or home health habilitative physical or occupational therapy.

All recommendations in this guideline reflect practices that are evidence-based and/or supported by broadly accepted clinical specialty standards.

Scope (1,2)

This guideline applies to all physical medicine practitioners. If a service can be self-administered safely and effectively by an unskilled person without the direct supervision of a therapist, then the service cannot be regarded as a skilled therapy service even if a therapist rendered the service. 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.

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

INDICATIONS

The following criteria must be addressed to justify the medical necessity of the prescribed treatment. Medically necessary services are reasonable or necessary, and require:

- Specific training, skills, and knowledge of a physical or occupational therapist to:
 - Diagnose, correct, or significantly improve/optimize a condition.
 - Prevent deterioration or development of additional physical and mental health conditions.
- Complexity of care that can only be safely and effectively performed by or under the general supervision of a skilled therapist.

Documentation (3,4,5)

- 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



- Diagnosis and date of onset and/or exacerbation of the condition
- Prior and current level of function
 - Identification of any underlying factors that have impacted current functional performance must also be noted.
- Re-evaluations must be performed at a minimum annually to show functional progress.
 - Provide evidence supporting medical necessity for the continuation of services.
 - Use current objective measures to show significant progress and support ongoing delays
 - Re-evaluations should include updated formal testing that is:
 - Age-appropriate
 - Norm-referenced
 - Standardized
 - Specific to the type of therapy provided.
- Skilled services being provided by other community service agencies and/or school systems.
 - Services should not duplicate those being provided by community programs or agencies.
 - Document coordination of services with other agencies.
 - o Document unavailable services.
- Evidence that the services are considered reasonable and planned treatments require the ongoing skills and knowledge of a therapist.
- Clinical updates at regular intervals or when additional care is requested and include:
 - Current objective measures
 - Progress towards goals
 - Requested frequency and duration of care.
 - o The patient's current level of function
 - o Any conditions that are impacting their 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
 - 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.
 - o Evidence of discharge planning
 - Measurable improvement and progress towards functional goals within an anticipated and reasonable timeframe toward a patient's maximum potential.
- Maintenance programs



- Skilled interventions rendered and objective details of how these interventions are preventing deterioration or making the condition more tolerable.
- Evidence 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.
- o Should have a plan of care that clearly reflects maintenance treatment.

Evaluation (6)

- Habilitative Physical or Occupational Therapy
 - Treatment is reasonable and appropriate for an individual with a progressive disorder and 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 or treatment has yielded no measurable functional progress over a reasonable amount of time.
- Establishing a delay or deficit
 - Formal testing/functional assessments (7,8)
 - Age-appropriate, norm-referenced, standardized, and specific to the therapy provided.
 - Test scores and interpretation should establish the presence of a significant motor or functional delay as defined by the specific test.
 - Raw scores are not sufficient to establish the presence of a delay.
 - Score reports should include percentile ranks and/or standard deviations from the mean as applicable for the test used.
 - 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 otherwise perform everyday tasks.
 - Orthopedic diagnoses not related to functional delay should include appropriate tests and measures specific to the deficit and the therapy provided.
 - When standardized testing cannot be completed, the documentation must clearly state the reason formal testing could not be done.
 - At minimum, re-testing must occur yearly, but may occur every 180 days.
 - Providers must assess patient status with the same testing instrument used in the initial evaluation or explain the reason for the change in testing instrument.
 - o In the absence of standardized testing or when test scores show skills within normal ranges, the documentation must include one of the following:
 - Detailed clinical observations and objective data to document the degree and severity of the condition.
 - A caregiver interview/questionnaire



- Informal assessment supporting Functional Mobility/ADL (Activities of Daily Living) deficits and the medical need for skilled services.
- In the case of feeding difficulties, the notes must clearly indicate a functional feeding delay as a result of underlying impairments.
 - Indications of a delay may include:
 - Gagging/choking
 - Oral motor or upper extremity coordination deficits
 - Maladaptive behaviors due to a food intolerance/aversion preventing adequate oral intake that contribute to malnutrition or decreased body mass index.
 - If the delay is the result of fine/oral motor or sensory delays or deficits, testing and detailed clinical observations of oral motor skills should be included in the documentation.
 - Parent report of limited food choices is not adequate to support the medical need for feeding therapy.
 - 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 are not medically necessary for picky eaters who:
 - Can eat and swallow normally.
 - Meet growth and developmental milestones.
 - □ Eat at least one food from all major food groups (protein, grains, fruits, etc.)
 - □ Eat more than 20 different foods.

Plan of Care (9)

- Evaluations and re-evaluations must include a plan of care.
- The plan of care should detail type, amount, duration, and frequency of therapy services required to achieve targeted outcomes.
- Short and long-term functional goals in the plan of care <u>should</u>:
 - Be SMART: Specific, Measurable, Attainable, Relevant, and Timed (10)
 - Include the date the goal was established and the date the goal is expected to be met.
 - Target the functional deficits identified during the assessment and promote attainment of age-appropriate developmental milestones, functional mobility and/or ADL skills.
- Short and long-term functional goals in the plan of care <u>should NOT</u>:
 - Have underlying factors, (performance skills, client factors, the environment) as the targeted outcome of long-term goals.
 - Have underlying factors (strength, range of motion, cognition) as the sole focus of short-term goals.



- The plan of care should include a reasonable anticipated timeframe to meet the established goals.
 - o If goals are not met within the expected timeframe, documentation should explain why they were not met and if the plan of care was adjusted accordingly.
 - If the plan of care was not adjusted, documentation must demonstrate why the skills of a therapist are still medically necessary to address the goals.
- Interventions in the plan of care must be:
 - Evidence-based, requiring the skills of a therapist to perform and/or teach the task.
 - o Chosen to address the targeted goals.
 - Representative of the best practices outlined by the corresponding national organizations.
 - Considerate of functional limitations outlined in the most recent evaluation/assessment.
 - Promote motor learning or relatively permanent differences in motor skill capability that can be transferred and generalized to new learning situations.
 - o Explicitly linked to the targeted goal/outcome they address.
 - Reinforced by the parents or other caregivers and can be practiced in the child's environment to sustain positive benefits.
- 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:
 - o Total visits from the start of care
 - Changes in objective measures
 - Updated outcome measure scoring and interpretation of results
 - Overall quantified progress towards each goal (including if the goal has or has not been met)
 - Modification of treatment interventions needed to meet goals
 - Goals updated as appropriate
 - Summary of patient's response (or lack thereof) to intervention
 - If the patient is not progressing, documentation of a revised plan of care is necessary, and must include specific barriers to progress.
 - Brief statement of the prognosis or potential for improvement in functional status
 - Updates to the frequency or amount of expected care in preparation for discharge

Frequency and Duration (11,12,13)

- Must be supported by skilled treatment interventions regardless of level or severity of delay.
- Must be commensurate with:
 - Patient's level of disability



- Medical and skilled therapy needs.
- Accepted standards of practice
- Clinical reasoning and current evidence
- Intense frequencies (on a case-by-case basis, > 3x/week for a short duration ≤4
 weeks) 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 patient's rehabilitation potential for achieving the goals identified.
 - Purpose of the intense frequency requested (e.g., during an acute phase, 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.
- High frequencies (3x/week for a short duration of 2-6 weeks)
 - Considered when documented delays are classified as severe as defined by the specific test utilized and supported by corresponding testing guidelines used in the evaluation.
 - Include 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 and details on why a higher frequency is more beneficial than a moderate or low frequency.
 - Considered when the treatment plan is rapidly evolving necessitating frequent updates to the home program.
 - Necessary in the acute phase
 - Progressive decline in frequency is expected within a reasonable time frame.
- Moderate frequency (2x/week)
 - Consistent with moderate delays as established in the general guidelines of formal assessments used in the evaluation.
 - Therapy provided 2x/week may be considered when documentation shows one or more of the following:
 - Patient is making very good functional progress toward goals.
 - Patient is in a critical period to gain new skills or restore function or is at risk of regression.
 - Licensed therapist needs to adjust the patient's therapy plan and home program weekly or more often than weekly based on their progress and medical needs.
 - Patient has complex needs requiring ongoing education of the responsible adult.
 - Each treatment session involves skilled and unique interventions that are not repetitive when compared to recent treatment sessions.



- Low frequency (≤ 1x/week)
 - One time per week or less is appropriate when:
 - Patient is making progress toward their goals, but the progress has slowed.
 - Patient is at risk of deterioration due to their medical condition.
 - Licensed therapist is required to adjust the patient's therapy plan and home program weekly to every other week based on the patient's progress.
 - o Every other week is supported appropriate when:
 - Medical condition is stable.
 - Patient is making progress.
 - Anticipated member will not regress with every other week therapy.
 - Less than every other week is appropriate when:
 - The patient cannot yet tolerate more frequent therapy sessions.
 - The patient has 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.
- Maintenance Level/Prevent Deterioration (e.g., every other week, monthly, every 3 months)
 - o Is appropriate when:
 - Therapy plan changes very slowly
 - Home program is at a level that may be managed by the patient or the responsible adult/caregiver.
 - Therapy plan requires infrequent updates by the skilled therapist.
 - Progress has slowed or stopped (documentation supports that ongoing skilled therapy is required to maintain the progress made or prevent deterioration)
 - Patient may be making limited progress toward goals or that goal attainment is extremely slow.
 - Factors are identified that inhibit the patient's ability to achieve established goals.
 - Documentation must show the following:
 - 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.
 - □ Skilled interventions rendered and objective details of how these interventions are preventing deterioration or making the condition more tolerable must be provided.
 - Patient and responsible caregiver have a continuing need for education, a



- periodic adjustment of the home program, or regular modification of equipment to meet the patient's needs.
- Specialized judgment, knowledge, and skills of a qualified therapist are required for the safe and effective performance of services.

Discontinuation of Treatment (14)

A discharge plan must be included in the plan of care.

- The discharge plan must indicate the plan to wean services if:
 - Patient has attained their goals.
 - No sustained, measurable functional improvement has been demonstrated.
 - Program can be carried out by caregivers or other non-skilled personnel.
- For members no longer showing functional improvement, a weaning process of one to two months should occur.
- Treatment can be discontinued if the patient:
 - Returned to expected level of function.
 - Adapted to impairment with assistive equipment or devices.
 - o Is able to perform ADLs with minimal to no assistance from caregiver.
 - Achieved maximum functional benefit from therapy.
 - Will no longer benefit from additional therapy
 - o Is unable to participate in the treatment plan or plan of care due to:
 - Medical, psychological, or social complications
 - Caregiver received instructions on the home treatment program and is able to demonstrate independence with the program.
 - Skills of a therapist are not needed to provide or supervise the service.
 - Standardized testing shows they no longer have a developmental delay (as defined by the specific test used).
 - Plateau in response to therapy or lack of significant progress towards therapy goals.
 - Is non-compliant.
 - Poor attendance of member or responsible caregiver
 - With therapy and home treatment program
 - Treatment ceases to be of therapeutic value.
- 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.
- Skilled care may be appropriate to resume after discharge if the patient shows signs
 of regression in function despite a comprehensive home program. Periodic episodes



of care may be needed over a lifetime to address specific needs or changes in condition resulting in functional decline.

CODING AND STANDARDS

Applicable Lines of Business

	CHIP (Children's Health Insurance Program)
\boxtimes	Commercial
\boxtimes	Exchange/Marketplace
\boxtimes	Medicaid
\boxtimes	Medicare Advantage

POLICY HISTORY

Date	Summary
July 2025	Health plan specific guideline created at the request of HMSA

LEGAL AND COMPLIANCE

Guideline Approval

Committee

Reviewed / Approved by Evolent Specialty Clinical Guideline Review Committee

Disclaimer

Evolent Clinical Guidelines do not constitute medical advice. Treating health care professionals are solely responsible for diagnosis, treatment, and medical advice. Evolent uses Clinical Guidelines in accordance with its contractual obligations to provide utilization management. Coverage for services varies for individual members according to the terms of their health care coverage or government program. Individual members' health care coverage may not utilize some Evolent Clinical Guidelines. A list of procedure codes, services or drugs may not be all inclusive and does not imply that a service or drug is a covered or non-covered service or drug. Evolent reserves the right to review and update this Clinical Guideline in its sole discretion. Notice of any changes shall be provided as required by applicable provider agreements and laws or regulations. Members should contact their Plan customer service representative for specific coverage information.



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Sensory Integration Therapy and Auditory Integration Therapy

Policy Number:	Current Effective Date:
MM.09.007	May 23, 2025
Lines of Business:	Original Effective Date:
HMO; PPO; QUEST Integration	May 01, 2015
Place of Service:	Precertification:
Outpatient	Not required

I. Description

Sensory integration therapy (SIT) has been proposed as a treatment of developmental disorders in patients with established dysfunction of sensory processing, particularly autism spectrum disorder. SIT may be offered by occupational and physical therapists who are certified in SIT. Auditory integration therapy (AIT) uses gradual exposure to certain types of sounds to improve communication in a variety of developmental disorders, particularly autism.

For individuals who have developmental disorders who receive SIT, the evidence includes randomized controlled trials, systematic reviews of these trials, and case series. The relevant outcomes are functional outcomes and quality of life. Due to the individualized approach to SIT and the large variations in patients' disorders, large multicenter randomized controlled trials are needed to evaluate the efficacy of this intervention. The most direct evidence on SIT outcomes derives from several randomized trials (RCTs). Although some of these trials demonstrated improvements for subsets of outcomes measured, they had small sample sizes, heterogeneous patient populations, and variable outcome measures. A RCT of 138 children ages 4 to 11 years published in 2022 found that sensory integration therapy for children with autism and sensory processing difficulties did not demonstrate clinical benefit above standard care. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

For individuals who have developmental disorders who receive AIT, the evidence includes several randomized controlled trials and systematic reviews of these trials. The relevant outcomes are functional outcomes and quality of life. For AIT, the largest body of literature relates to its use in autism spectrum disorder. Several systematic reviews of AIT in the treatment of autism have found limited evidence to support its use. No comparative studies identified evaluated use of AIT for other conditions. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

II. Policy Criteria

Sensory integration therapy and auditory integration therapy are not covered because they are not known to be effective in improving health outcomes.

III. Administrative Guidelines

A. The provider cannot bill or collect charges for these services unless a written acknowledgement of financial responsibility, specific to the service, is obtained from the Member prior to the time services are rendered.

- B. Patients requesting services that are not covered should be informed that they will be responsible to pay for the services. To prevent misunderstandings about financial responsibility, the provider may ask the patient to sign an Acknowledgement of Financial Responsibility prior to performing the services.
- C. Applicable codes

CPT Code	Description
97533	Sensory integrative techniques to enhance sensory processing and promote
	adaptive responses to environmental demands, direct (one-on-one) patient
	contact, each 15 minutes

ICD-10-CM Code	Description
F84.0-F84.9	Pervasive developmental disorders code range (includes infantile autism, etc.)

IV. Scientific Background

The goal of SIT is to improve how the brain processes and adapts to sensory information, as opposed to teaching specific skills. Therapy usually involves activities that provide vestibular, proprioceptive, and tactile 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.

AIT - also known as auditory integration training, auditory enhancement training, audio-psychophonology - involves having individuals listen to music modified to remove frequencies to which they are hypersensitive, with the goal of gradually increasing exposure to sensitive frequencies. Although several methods of AIT have been developed, the most widely described is the Berard method, which involves two, half-hour sessions per day separated by at least three hours, over ten consecutive days, during which patients listen to recordings. AIT has been proposed for individuals with a range of developmental and behavioral disorders, including learning disabilities, autism spectrum disorder, pervasive developmental disorder, and attention-deficit/hyperactivity disorder. Other methods include the Tomatis method, which involves listening to electronically modified music and speech, and Samonas Sound Therapy, which involves listening to filtered music, voices, and nature sounds.

Regulatory Status

Sensory integration therapy is a procedure and, as such, is not subject to regulation by the U.S. Food and Drug Administration. No devices designed to provide AIT have been cleared for marketing by the Food and Drug Administration.

Rationale

This evidence review was created in April 2000 and has been updated regularly with searches of the MEDLINE database. The most recent literature update was performed through February 22, 2024.

Evidence reviews assess the clinical evidence to determine whether the use of technology improves the net health outcome. Broadly defined, health outcomes are length of life, quality of life (QOL), and ability to function, including benefits and harms. Every clinical condition has

specific outcomes that are important to patients and managing the course of that condition. Validated outcome measures are necessary to ascertain whether a condition improves or worsens; and whether the magnitude of that change is clinically significant. The net health outcome is a balance of benefits and harms.

To assess whether the evidence is sufficient to draw conclusions about the net health outcome of technology, 2 domains are examined: the relevance, and quality and credibility. To be relevant, studies must represent 1 or more intended clinical use of the technology in the intended population and compare an effective and appropriate alternative at a comparable intensity. For some conditions, the alternative will be supportive care or surveillance. The quality and credibility of the evidence depend on study design and conduct, minimizing bias and confounding that can generate incorrect findings. The randomized controlled trial (RCT) is preferred to assess efficacy; however, in some circumstances, nonrandomized studies may be adequate. RCTs are rarely large enough or long enough to capture less common adverse events and long-term effects. Other types of studies can be used for these purposes and to assess generalizability to broader clinical populations and settings of clinical practice.

Promotion of greater diversity and inclusion in clinical research of historically marginalized groups (e.g., People of Color [African-American, Asian, Black, Latino and Native American]; LGBTQIA (Lesbian, Gay, Bisexual, Transgender, Queer, Intersex, Asexual); Women; and People with Disabilities [Physical and Invisible]) allows policy populations to be more reflective of and findings more applicable to our diverse members. While we also strive to use inclusive language related to these groups in our policies, use of gender-specific nouns (e.g., women, men, sisters, etc.) will continue when reflective of language used in publications describing study populations.

Sensory Integration Therapy

Clinical Context and Purpose

The purpose of SIT in individuals who have developmental disorders is to provide a treatment option that is an alternative to or an improvement on existing therapies.

The following PICO was used to select literature to inform this review.

Populations

The relevant population of interest is individuals with developmental disorders.

Interventions

The treatment being considered is the use of SIT. The treatment sessions are often provided as part of a comprehensive occupational therapy or cognitive rehabilitation therapy and may last for more than one year.

Comparators

The following practices are currently being used to treat developmental disorders; specialized developmentally appropriate interventions for specific developmental disorders.

Outcomes

The general outcomes of interest are symptoms, change in disease status, functional outcomes and quality of life (QOL). Follow-up of at least six months would be desirable to assess outcomes.

Schaaf et al (2014) published an overview of current measurement issues in sensory integration. They proposed several changes to the outcomes used in sensory integration research, as follows:

- "Additional measures ... to ensure a comprehensive assessment of the sensory and motor factors that may be influencing function and participation";
- "Assessment measures ... to address a wider age range"
- Neurophysiologic studies.
- "Fidelity to the core principles of sensory integration therapy"
- "studies ... to evaluate the dosage of therapy to understand the best candidates for intervention and the appropriate intensity and frequency of intervention";
- "Outcomes that are meaningful to clients and sensitive to the changes observed after intervention."

The Sensory Processing Disorders Scientific Workgroup (2007) has also discussed the methodologic challenges of conducting intervention effectiveness studies of dynamic interactional processes, the lack of scientific evidence to support current practice, and methods for improving the quality of research in this area.

Study Selection Criteria

Methodologically credible studies were selected using the following principles:

- To assess efficacy outcomes, comparative controlled prospective trials were sought, with a preference for RCTs
- In the absence of such trials, comparative observational studies were sought, with a preference for prospective studies.
- To assess long-term outcomes and adverse events, single-arm studies that capture longer periods of follow-up and/or larger populations were sought.
- Studies with duplicative or overlapping populations were excluded.

Review of Evidence

Systematic Reviews

Several systematic reviews have addressed the use of SIT in various clinical conditions (Tables 1 and 2). Four of the 5 systematic reviews included in this evidence review pertain to studies evaluating SIT for autism spectrum disorder (ASD), while 1 included studies in individuals with a broader range of developmental disabilities.

Table 1. Comparison of Studies Included in Systematic Reviews of Sensory Integration Therapy

Randomized Controlled Trials (RCTs)	Weitlauf et al (2017)	Case-Smith et al (2015)	May-Benson et al (2010)
Carte et al (1984)			•
Fazlioðlu et al (2008)	•	•	
Grimwood et al (1980)			•
Humphries et al (1990)			•
Humphries et al (1992)			•
Humphries et al (1993)			•
Iwanaga et al (2014)	•		
Miller et al (2007)			•
Morrison et al 1986)			•
Pfeiffer et al (2011)	•	•	
Piravej et al 2009)			
Polatajko et al (1991)			•
Reilly et al (1983)			
Schaaf et al (2013)	•	•	
Werry et al (1990)			•
White (1979)			•
Wilson et al (1992)			•
Wilson et al (1994)			•
Woo et al (2013)			
Ziviani et al (1982)			•

Other Case Study Designs

	Weitlauf et al	Case-Smith et	Brondino et al	Watling and	May-Benson
	(2017)	al (2015)	(2015)	Hauer (2015)	et al (2010)
Allen et al (1995)					•
Ayres (1972)					•
Ayres (1977)					•
Bagatell et al (2010)		•		•	
Bullock et al (1978)					•
Bundy et al (2007)					•
Candler et al (2003)					•
Case-Smith et al (1999)					•
Cox et al (2009)		•		•	
Davis et al (2011)		•			
Devlin et al (2009)		•			
Devlin et al (2011)		•		•	
Fertel-Daly (2001)		•			
Hodgetts et al (2010)		•			
Hodgetts et al (2011)		•		•	
Kane et al (2004)		•			
Kinnealey et al (2012)				•	
Leemrijse et al (2000)					•
Leew et al (2010)		•		•	
Linderman et al (1999)					•
Miller et al (2007)					•
Ottenbacher et al (1979)					•
Ottenbacher et al					
(1982)					•
				•	
Quigley et al (2011)		•		•	
Reichow et al (2010)		•		•	
Roberts et al (2007)					•
Schaaf et al (2012)		•			

Schilling et al (2004)	•			
Schroeder et al (1982)				•
Smith et al (2005)	•			
Thompson et al 2011		•	•	
Umeda et al (2011)			•	
Van Rie et al (2009)	•			
Watling et al (2007)			•	
Watling et al (2010)	•			
Wuang et al (2010)			•	

RCTs: randomized controlled trials

Table 2. Characteristics of Systematic Reviews of Sensory Integration Therapy

Study	Search Dates	Studies	Populations
Case-Smith et al (2015)	2000 - 2012	2 RCTs, 3 other design	ASD
May-Benson et al (2010)	1972-2007	13 RCT, 14 other designs	Children with difficulty processing and integrating sensory information
Weitlauf et al (2017)	2010-2016	3 RCT, 1 other design	ASD

ASD: autism spectrum disorder; RCT: randomized controlled trial

In a systematic review conducted for the Agency for Healthcare Research and Quality (AHRQ), Weitlauf et al (2017) evaluated the effectiveness and safety of a variety of interventions targeting sensory challenges in ASD. The reviewers included 3 RCTs and 1 retrospective cohort study of sensory-integration-based approaches, defined as interventions using combinations of sensory and kinetic components, such as materials with different textures, touch/massage, swinging and trampoline exercises, and balance and muscle resistance exercises. One study was rated low risk of bias, 1 moderate, and 2 high risk of bias. Significant heterogeneity across studies in interventions and outcome measures precluded meta-analysis. In 3 of 4 studies, sensory-related measures and motor skills measures improved for children receiving the sensory-integration based intervention, however the strength of this evidence was rated low due to small sample sizes and short study durations. The studies were also limited by a lack of blinding when parent-reported outcome measures were used. The reviewers concluded, "Although some therapies may hold promise and warrant additional study, substantial needs exist for continuing improvements in methodologic rigor in the field."

Case-Smith et al (2015) updated a systematic review on sensory processing interventions, including SIT, which they defined as clinic-based interventions that use sensory-rich, child-directed activities to improve a child's adaptive responses to sensory experiences, and sensory-based interventions (defined as adult-directed sensory modalities applied to the child to improve behaviors associated with modulation disorders), for children with ASD with concurrent sensory processing problems. This review was designed to focus on interventions that activate the somatosensory and vestibular systems for patients with ASD with co-occurring sensory processing problems. Nineteen studies published since 2000 were included, 5 of which evaluated SIT in patients with ASD and sensory processing disorders. 2studies reviewed were RCTs; both were small (n=20 and n=17 in the SIT groups). Reviewers noted the studies showed low or low-to-moderate effects and concluded that "It is premature to draw conclusions as to whether SIT for children with ASD, which is designed to support a child's intrinsic motivation and sense of internal control, is ultimately effective."

May-Benson and Koomar (2010) published a systematic review of SIT, identifying 27 research studies (13 randomized trials) that met their inclusion criteria. Most studies had been performed with children who had learning or reading disabilities; there were two case reports/small series on the effect of SIT in children with ASD. Reviewers concluded that although the sensory integration approach might result in positive outcomes, findings were limited because of small sample sizes, variable intervention dosages, lack of fidelity to interventions, and selection of outcomes that might not be meaningful or might not change with the treatment provided.

Randomized Controlled Trial

The SENsory Integration Therapy for sensory processing difficulties in children with Autism spectrum disorder (SenITA) RCT was published more recently and not included in the systematic reviews discussed above (Table 3). The trial was funded by the National Institute for Health and Care Research (UK) and reported by Randell et al (2022). A total of 138 children ages 4 to 11 years with an autism diagnosis or sensory processing difficulties were randomized to Ayres Sensory Integration® therapy delivered in 26 1-hour sessions over 26 weeks (intensive phase), followed by 2 sessions per month for 2 months and then 1 telephone session per month for 2 months (tailoring phase). The comparator was usual care, which was defined as awaiting services or receiving sensory-based intervention not meeting fidelity criteria for sensory integration. Outcomes were measured at 6 and 12 months post randomization. The primary outcome was irritability/agitation (as measured by the corresponding Aberrant Behavior Checklist subscale), indicative of challenging behavior, at 6 months. Secondary outcomes included other problem behaviors, adaptive behaviors and functioning, socialization, caregiver stress, and quality of life. Outcome assessors were blinded to treatment allocation. Study limitations are shown in Tables 4 and 5.

Sensory integration therapy did not demonstrate clinical benefit above standard care (adjusted mean difference between groups on the primary outcome 0.40 [95% CI –2.33 to 3.14; P =.77]). No main intervention effects were observed, and sensitivity analyses did not alter the interpretation of results. Subgroup analyses suggest that sensory integration therapy may work better for boys and those with a comorbid diagnosis of ADHD. However, these subgroup analyses were exploratory and not powered to detect effects.

Table 3. Randomized Controlled Trial of Sensory Integration Therapy in Children with Autism

and Sensory Processing Difficulties- Characteristics

Study	Location	Inclusion/Excl	Intervention	Comparator	Main Results
•		usion Criteria			
Randell et al	England and	Children ages 4	N = 69	N = 69	Primary
(2022)	Wales	to 11years	Ayres Sensory	Usual care,	Outcome
,		with a	Integration	defined as	(irritability/agit
		diagnosis of	therapy	awaiting	ation at
		autism or	delivered in 26	services or	6months on
		probable or	1-hoursessions	receiving	Aberrant
		likely autism	over26 weeks2	sensory-based	Behavior
		(defines as	sessions per	intervention	Checklist):
		undergoing	week for 10	not meeting	
		assessment); in	weeks	fidelity criteria	Mean score:
		mainstream	(intensive	for sensory	Usual care 18.8
		primary	phase),	integration	(SD 10.48)
		education;	followed by		Intervention
İ		definite or	2sessions per		18.5 (SD 9.33)
		probable SPDs	month for2		
			months and		Adjusted mean
		Exclusions:	then 1		difference
		currently	telephone		between
		undergoing or	session per		groups 0.40
		had previously	month for 2		(95% CI-2.33
		undergone SIT	months		to 3.14; P =.77)
		or applied	(tailoring		
		behavior	phase)		Conclusions
		analysis			from primary
		therapy			analyses
		Recruitment			unaffected by
		via services			sensitivity
		and self-			analyses
		referral			accounting for
					missing data,
					intervention
					receipt (i.e.
					dose) or
					theCOVID-19
					pandemic.
					No evidence of
					meaningful
					intervention
					effects was
					found at 6 or
					12 months
					across
					behavioral,
					adaptive
					functioning,
					socialization,
					caregiver
				1	Caregiver

		stress, health
		utility or
		quality-of-life
		measures.

CI: confidence interval; SD: standard deviation; SPD: sensory processing difficulties.

Table 4. Study Relevance Limitations

Study	Population ^a	Intervention ^b	Comparator ^c	Outcomesd	Duration of Follow-up ^e
Randell et al (2022)	4. The population Was representative of children within autism services, although girls and minority ethnic boys were likely to be under-represented in both the current study and the wider population of Children diagnosed with autism	5. Delivery of the intervention varied across regions			

The study limitations stated in this table are those notable in the current review; this is not a comprehensive gaps assessment.

Table 5. Study Design and Conduct Limitations

Table 31 Stady Sesign and Contact Emilitations						
Study	Allocation ^a	Blindingb	Selective	Data Completeness ^d	Power ^e	Statistical ^f
			Reporting ^c			
Randell				7. caregiver-reported		
et al				goal performance		
(2022)				not measured in		
				control arm		

The study limitations stated in this table are those notable in the current review; this is not a comprehensive gaps assessment.

^a Population key: 1. Intended use population unclear; 2. Study population is unclear; 3. Study population not representative of intended use; 4, Enrolled populations do not reflect relevant diversity; 5. Other.

^b Intervention key: 1. Not clearly defined; 2. Version used unclear; 3. Delivery not similar intensity as comparator; 4. Not the intervention of interest (e.g., proposed as an adjunct but not tested as such); 5: Other.

^c Comparator key: 1. Not clearly defined; 2. Not standard or optimal; 3. Delivery not similar intensity as intervention; 4. Not delivered effectively; 5. Other.

^d Outcomes key: 1. Key health outcomes not addressed; 2. Physiologic measures, not validated surrogates; 3. Incomplete reporting of harms; 4. Not establish and validated measurements; 5. Clinically significant difference not prespecified; 6. Clinically significant difference not supported; 7. Other.

^e Follow-Up key: 1. Not sufficient duration for benefit; 2. Not sufficient duration for harms; 3. Other.

^a Allocation key: 1. Participants not randomly allocated; 2. Allocation not concealed; 3. Allocation concealment unclear; 4. Inadequate control for selection bias; 5. Other.

^b Blinding key: 1. Participants or study staff not blinded; 2. Outcome assessors not blinded; 3. Outcome assessed by treating physician; 4. Other.

^c Selective Reporting key: 1. Not registered; 2. Evidence of selective reporting; 3. Evidence of selective publication; 4. Other

^d Data Completeness key: 1. High loss to follow-up or missing data; 2. Inadequate handling of missing data; 3. High number of crossovers; 4. Inadequate handling of crossovers; 5. Inappropriate exclusions; 6. Not intent to treat analysis (per protocol for noninferiority trials); 7. Other.

^e Power key: 1. Power calculations not reported; 2. Power not calculated for primary outcome; 3. Power not based on clinically important difference; 4. Other.

f Statistical key: 1. Analysis is not appropriate for outcome type: (a) continuous; (b) binary; (c) time to event; 2. Analysis is not appropriate for multiple observations per patient; 3. Confidence intervals and/or p values not reported; 4. Comparative treatment effects not calculated; 5. Other.

Section Summary: Sensory Integration Therapy

The most direct evidence related to outcomes from SIT comes from randomized trials and systematic reviews of these trials. Although certain studies demonstrated some improvements on subsets of the outcomes measured, the studies were limited by small sample sizes, heterogeneous patient populations, and variable outcome measures. A RCT of 138 children ages 4 to 11 years published in 2022 found that sensory integration therapy for children with autism and sensory processing difficulties did not demonstrate clinical benefit above standard care. As a result, the evidence is not sufficiently robust to draw conclusions about the effects of- and the most appropriate patient populations for- SIT.

Auditory Integration Therapy

Clinical Context and Purpose

The purpose of AIT in patients who have developmental disorders is to provide a treatment option that is an alternative to or an improvement on existing therapies.

The question addressed in this evidence review is: does the use of AIT in patients who have developmental disorders improve net health outcomes?

The following PICO was used to select literature to inform this review.

Populations

The relevant population(s) of interest are patients with developmental disorders. Although AIT has been proposed as a therapy for a number of neurobehavioral disorders, the largest body of evidence, including systematic reviews, relates to its use in ASD.

Interventions

The treatment being considered is the use of AIT. Auditory integration therapy involves having individuals listen to music modified to remove frequencies to which they are hypersensitive, with the goal of gradually increasing exposure to sensitive frequencies.

Comparators

The following practices are currently being used to treat developmental disorders: specialized interventions for specific developmental disorders.

Outcomes

The general outcomes of interest are symptoms, change in disease status, functional outcomes and QOL.

Follow-up of at least 6 months would be desirable to assess outcomes.

Study Selection Criteria

Methodologically credible studies were selected using the principles described in the first indication.

Review of Evidence

Systematic Reviews

In their systematic review of sensory interventions conducted for AHRQ, Weitlauf et al (2017) included 4 RCTs of auditory integration therapy. Two small, short-term RCTs with moderate risk of bias reported no significant differences between auditory integration and control groups in language outcomes assessed on parent, teacher, and clinician observation measures. Two other RCTs, reported in a single publication, reported some parent-rated improvement in hearing sensitivity, spontaneous speech, listening, and behavioral organization, but no difference in other behavioral domains rated. Overall, the reviewers concluded that there is low strength evidence that auditory integration-based approaches do not improve language outcomes.

A Cochrane review (2011) evaluated AIT along with other sound therapies for ASD. Included were 6 RCTs on AIT and 1 on Tomatis therapy, comprising a total of 182 subjects (age range, 3-39 years). For most trials, the control condition was listening to unmodified music for the same amount of time as the active treatment group. Allocation concealment was inadequate for all trials, and 5 trials had fewer than 20 participants. Meta-analyses could not be conducted. Three studies did not demonstrate any benefit of AIT over control conditions, and three studies had outcomes of questionable validity or outcomes that were not statistically significant. Reviewers found no evidence that AIT is an effective treatment for ASD; however, evidence was insufficient to prove that it is not effective.

In the systematic review examining complementary and alternative therapies for ASD, Brondino et al (2015; described above) identified the same 6 RCTs of AIT included in the 2011 Cochrane review. Like the Cochrane review, Brondino et al (2015) concluded that the largest studies did not report improvements with AIT.

Section Summary: Auditory Integration Therapy

The largest body of evidence on the use of AIT relates to treatment of ASD. A 2011 Cochrane review and several earlier systematic reviews generally found that studies of AIT failed to demonstrate meaningful clinical improvements. No subsequent comparative studies of AIT were identified.

V. Supplemental Information

The purpose of the following information is to provide reference material. Inclusion does not imply endorsement or alignment with the evidence review conclusions.

Practice Guidelines and Position Statements

American Academy of Pediatrics

A 2012 policy statement by the American Academy of Pediatrics on SIT for children with developmental and behavioral disorders stated that "occupational therapy with the use of sensory-based therapies may be acceptable as one of the components of a comprehensive treatment plan. However, parents should be informed that the amount of research regarding the effectiveness of sensory integration therapy is limited and inconclusive." The American Academy of Pediatrics indicated that these limitations should be discussed with parents, along with instruction on how to evaluate the effectiveness of a trial period of SIT.

In 2020, a clinical report by the American Academy of Pediatrics was published on the identification, evaluation, and management of children with autism spectrum disorder (ASD). Regarding sensory integration therapy, the report stated, "Although sensory-based therapies are among the most commonly requested therapies by caregivers, the evidence supporting their general use remains currently limited". Regarding auditory integration therapy, the report stated, "Evidence to date does not support the use of auditory integration training, in which an individual listens to altered sounds through headphones in an effort to change auditory or other processing".

American Occupational Therapy Association

The 2015 American Occupational Therapy Association (AOTA) guidelines stated: "American Occupational Therapy Association (AOTA) recognizes sensory integration as one of several theories and methods used by occupational therapists and occupational therapy assistants working with children in public and private schools...to "enhanc[e] a person's ability to participate in life through engagement in everyday activities...When children demonstrate sensory, motor, or praxis defects that interfere with their ability to access the general education curriculum, occupational therapy using an sensory integration approach is appropriate".

In 2011, the American Occupation Therapy Association (AOTA) published evidence-based occupational therapy practice guidelines for children and adolescents with challenges in sensory processing and sensory integration. The AOTA gave a level C recommendation for SIT for individual functional goals for children, for parent-centered goals, and for participation in active play in children with sensory processing disorder, and to address play skills and engagement in children with autism. A level C recommendation is based on "...weak evidence that the intervention can improve outcomes, and the balance of the benefits and harms may result either in a recommendation that occupational therapy practitioners routinely provide the intervention ... or in no recommendation because the balance of the benefits and harm is too close to justify a general recommendation." Specific performance skills evaluated were motor and praxis skills, sensory-perceptual skills, emotional regulation, and communication and social skills. There was insufficient evidence to recommend SIT for academic and psychoeducational performance (e.g., math, reading, written performance).

American Speech-Language-Hearing Association

In 2002, the American Speech-Language-Hearing Association Work Group on Auditory Integration Therapy concluded that auditory integration therapy has not met scientific standards for efficacy that would justify its practice by audiologists and speech-language pathologists.

U.S. Preventive Services Task Force Recommendations

Not applicable.

Medicare National Coverage

There is no national coverage determination. In the absence of a national coverage determination, coverage decisions are left to the discretion of local Medicare carriers.

Ongoing and Unpublished Clinical Trials

Some currently unpublished trials that might influence this review are listed in Table 6.

Table 6. Summary of Key Trials

NCT Number	Trial Name	Planned Enrollment	Completion Date
NCT02536365	Sensory Integration Therapy in Autism: Mechanisms and Effectiveness	180	Dec 2021
NCT04696133	Therapeutic Outcomes of Sensory Integration Versus Fine Motor Intervention in Children with Autism	30	Dec 2021

NCT: national clinical trial.

VI. Important Reminder

The purpose of this Medical Policy is to provide a guide to coverage. This Medical Policy is not intended to dictate to providers how to practice medicine. Nothing in this Medical Policy is intended to discourage or prohibit providing other medical advice or treatment deemed appropriate by the treating physician.

Benefit determinations are subject to applicable member contract language. To the extent there are any conflicts between these guidelines and the contract language, the contract language will control.

This Medical Policy has been developed through consideration of the medical necessity criteria under Hawaii's Patients' Bill of Rights and Responsibilities Act (Hawaii Revised Statutes §432E-1.4), or for QUEST members, under Hawaii Administrative Rules (HAR 1700.1-42), generally accepted standards of medical practice and review of medical literature and government approval status.

HMSA has determined that services not covered under this Medical Policy will not be medically necessary under Hawaii law in most cases. If a treating physician disagrees with HMSA's determination as to medical necessity in a given case, the physician may request that HMSA reconsider the application of the medical necessity criteria to the case at issue in light of any supporting documentation.

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VIII. Policy History

Action Date	Action
December 11, 2014	Policy reviewed by Medical Director, Larry Burgess, M.D.
December 16, 2014 Policy approved by Medical Directors	
December 19, 2014	Policy approved by UMC
May 01, 2015	Effective after 90 days' notice
November 23, 2016	Policy reviewed by Medical Director, Larry Burgess, M.D.
December 20, 2016	Policy approved by Medical Directors
December 30, 2016	Policy approved by UMC
March 15, 2017	Policy reviewed by Medical Director, Larry Burgess, M.D.
April 04, 2017	Policy approved by Medical Directors
April 28, 2017	Policy approved by UMC
April 17, 2018	Policy reviewed by Medical Director, Larry Burgess, M.D.
May 01, 2018	Policy approved by Medical Directors
May 25, 2018	Policy approved by UMC
April 29, 2019	Policy reviewed by Medical Director, Larry Burgess, M.D.
May 07, 2019	Policy approved by Medical Directors
May 24, 2019	Policy approved by UMC

Policy reviewed by Medical Director, Larry Burgess, M.D.
Toncy reviewed by intedical birector, Early burgess, IVI.b.
Policy approved by Medical Directors
Policy approved by UMC
Policy reviewed by Medical Director, Larry Burgess, M.D.
Policy approved by Medical Directors
Policy approved by UMC
Policy reviewed by Medical Director, Larry Burgess, M.D.
Policy approved by Medical Directors
Policy approved by UMC
Policy revised to meet WCAG compliance; Expired links removed or updated
Policy reviewed by Medical Director, Larry Burgess, M.D.
Policy approved by Medical Directors
Policy approved by UMC
Policy reviewed by Medical Director, Larry Burgess, M.D.
Policy approved by Medical Directors
Policy approved by UMC
Policy reviewed by Medical Director, Larry Burgess, M.D.
Policy approved by Medical Directors
Policy approved by UMC



Evolent Clinical Guideline 1510 for Record Keeping and Documentation Standards: Physical Medicine

Guideline Number:

Evolent_CG_1510

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STATEMENT

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.

Purpose

This guideline will assist the physical therapist, occupational therapist, and/or speech-language pathologist in creating and maintaining complete and appropriate clinical records and documentation.

All recommendations in this guideline reflect practices that are evidence-based and/or supported by broadly accepted clinical specialty standards.

Scope

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.

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.

Special Note

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.

MEDICAL RECORD CONTENT REQUIREMENTS (1,2,3)

General Guidelines

- Documentation should clearly reflect why the skills of a practitioner are needed/the care is <u>medically necessary</u>
- All records (both digital and handwritten) must be legible: the ability of at least two people to read and understand the documents.
- Documentation should be complete and include:
 - o Practitioner's signature and credentials



- Appropriately dated chart entries
- o Patient identifications on each page
- 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.

Evaluation/Re-Evaluation

Initial evaluations and re-evaluations including plan of care (<u>see below</u>) must be performed by a state-licensed PT, OT, SLP, MD, DO or DPM and should document:

- Medical need for a course of treatment through objective findings and subjective self or caregiver reporting
- Pertinent history and general demographics including:
 - Past or current treatment for the same condition
 - Baseline evaluation including current and prior functional status (submit for review)
- Copy of discharge summary including a written letter from the member stating when services ended or a specific reference to the date the member chose 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.
- 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.
 - o Assessment tools used during the evaluation should be:
 - Valid
 - Reliable
 - Relevant to the condition(s) being addressed
 - Supported by the appropriate national therapy best practices guidelines.
 - 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/inability to perform everyday tasks
- 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.
- Medical need for skilled services
- The reason formal testing could not be completed.
- Functional outcome assessment and/or standardized test results to include:
 - Raw scores
 - Standardized scores
 - Score interpretation.
- Detailed clinical observations and 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/SLP)
- Information regarding child's involvement in home and community programs (for Habilitative OT/PT/SLP)

Daily Notes

Should include the following:

- Clear evidence of skilled treatment interventions that cannot be conducted solely by non-skilled personnel.
- Assessment of patient's response or non-response to intervention and plan for subsequent treatment sessions, assessments, or updates
- Any significant, unusual, or unexpected changes in clinical status

Treatment Plan or Plan of Care

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. This includes the use of telehealth rather than on-site treatment.

The plan of care should include the following:

- Meaningful clinical observations
- Patient's response to the evaluation process
- Interpretation of the evaluation results including:
 - o Prognosis for improvement
 - o Recommendations for therapy services amount, frequency, and duration
- Short and long-term goals that are required to achieve targeted outcomes.
 - SMART (Specific, Measurable, Attainable, Realistic, and Time-bound)
 - Detail the type of intervention that must be:



- Skilled treatment interventions, regardless of level of severity of deficit or delay
- Evidence-based
- Chosen to address the targeted goals and/or outcomes.
- Representative of the best practices outlined by the corresponding national organizations.
- 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.
- Amount, duration, and frequency
 - The frequency and duration must be commensurate with:
 - Patient's level of disability
 - Medical and skilled therapy needs
 - Accepted standards of practice
 - Clinical reasoning and current evidence
 - \Box Frequency and duration of skilled services must also be in accordance with the following $^{(4,5,6)}$:
 - ◆ Intense frequencies (≥ 3x/week) require additional documentation and testing to support a medical need (achieve an identified new skill or recover a function with specific, achievable goals within the requested period)
 - Include details on why a higher frequency is more beneficial than a moderate or low frequency.
 - Higher frequencies may be considered when delays are classified as severe (indicated by corresponding objective measures and/or testing guidelines used in the evaluation)
 - More intensive frequencies may be necessary in the acute phase (progressive decline in frequency is expected within a reasonable time)
 - Moderate frequency (2x/week) should be consistent with moderate delays (established by objective measures and/or the general guidelines of formal assessments in the evaluation)
 - ♦ Frequency may be used for ongoing care when documentation supports it as being clinically effective toward achieving the functional goals in the treatment plan within a reasonable time.
 - ◆ 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
 - Visits or units requested must not exceed the frequency and duration supported in the plan of care.
- Linked to functional limitations outlined in the most recent valuation or assessment.



- Additional factors may be considered on a case-by-case basis.
- Expected caregiver involvement in the patient's treatment
- Educational plan, including:
 - Home exercises
 - o Activities of Daily Living (ADL) modifications
 - o Anticipated discharge recommendations including:
 - Education of the member in a home program
 - Primary caregiver education (when applicable)
- 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.
 - o Functional limitations do not support the rate of care requested (stated above)
 - Treatment is provided without a treatment plan, functional goals, or recent, sustained improvement.
- 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 measures
- Updated outcome measure scoring and interpretation of results
- Overall quantified progress towards each goal (including if goal has been met or not met)
- Modification of treatment interventions needed to meet goals.
- Goals updated as appropriate.
- Summary of a patient's response (or lack thereof) to intervention
- Statement (brief) of the prognosis or potential for improvement in functional status
- Updates to the frequency or amount of expected care in preparation for discharge

Note: Treatment must not be focused on returning to activities beyond normal daily living, including but not limited to return to sports, recreational activities, and/or work-specific tasks.

Maintenance Care

Maintenance level of therapy services may be considered when a member requires skilled therapy for ongoing periodic assessments, consultations, and treatment.

- Goals in the plan of care must reflect that care is focused on maintaining the current level of function 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 documentation must clearly demonstrate that the specialized judgement, 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.
- It is expected that evidence will be provided regarding the implementation of a comprehensive home program with indications of compliance by the member to the home program for maximum benefit of therapy.

Lack of Information

Reviewers can determine that claims or 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, and insufficient detail showing clear evidence supporting recent significant progress with treatment, such as lacking baseline/updated objectives and goals, or specific plan of care) may result in 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.

CODING AND STANDARDS

Applicable Lines of Business

\boxtimes	CHIP (Children's Health Insurance Program)
\boxtimes	Commercial
\boxtimes	Exchange/Marketplace
\boxtimes	Medicaid
\boxtimes	Medicare Advantage

BACKGROUND

Medical Necessity (1,2,7)

Medically necessary services are reasonable or necessary services that require the specific training, skills, and knowledge of a physical or occupational therapist and/or speech/language pathologist 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 practitioner.

- 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.
 - Simply because a licensed practitioner furnishes it.
 - If a service can be self-administered or safely and effectively conducted by an unskilled person, without the direct supervision of a practitioner, then it cannot be regarded as a skilled service even though a licensed practitioner rendered the service.
 - The unavailability of a competent person to provide a non-skilled service resulting in the non-skilled service being rendered by a licensed practitioner does not make the service provided a skilled service.
 - They include repetitive activities (exercises, skill drills) which do not require a licensed practitioner's expertise (knowledge, clinical judgment and decisionmaking abilities) and can be learned and performed by the patient or caregiver.
 - o They are activities for general fitness and flexibility, sports-specific training enhancement or general tutoring for improvement in academic performance.

Medically necessary care must be:

- **Contractual** all health care services are determined by the practitioner's contract with the payer and individual health plan benefits.
- Within Scope of Practice all health care services are limited to the scope of practice under all applicable state and national health care boards.
- Within Standard of Practice all health care services must be within the practitioner's generally accepted standard of practice.
- Considerate of Patient Safety all health care services must be delivered in the safest possible manner.
- A 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.
- Considerate of Setting all health care services must be delivered in the least intensive setting.
- Considerate of 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.
- **Supported by Clinical Guidelines** health care services meet all of the Clinical Guidelines of this organization.



POLICY HISTORY

Date	Summary	
November 2024	 This guideline replaces Evolent Clinical Guideline 606-01 for Record Keeping and Documentation: Physical Medicine Updated references 	
December 2023		
December 2023	"Maintenance Section" added	

LEGAL AND COMPLIANCE

Guideline Approval

Committee

Reviewed / Approved by Evolent Specialty Clinical Guideline Review Committee

Disclaimer

Evolent Clinical Guidelines do not constitute medical advice. Treating health care professionals are solely responsible for diagnosis, treatment, and medical advice. Evolent uses Clinical Guidelines in accordance with its contractual obligations to provide utilization management. Coverage for services varies for individual members according to the terms of their health care coverage or government program. Individual members' health care coverage may not utilize some Evolent Clinical Guidelines. A list of procedure codes, services or drugs may not be all inclusive and does not imply that a service or drug is a covered or non-covered service or drug. Evolent reserves the right to review and update this Clinical Guideline in its sole discretion. Notice of any changes shall be provided as required by applicable provider agreements and laws or regulations. Members should contact their Plan customer service representative for specific coverage information.



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- 1. Occupational Therapy Practice Framework: Domain and Process—Fourth Edition. Am J Occup Ther. 2020; 74: 7412410010p1 7412410010p87. 10.5014/ajot.2020.74S2001.
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- 7. Centers for Medicare and Medicaid Services. Regulations and Guidance Manuals (Internet Only Manuals) Medicare Benefit Policy Manual Chapter 15: Medical and Other Health Services 220.3 Documentation Requirements for Therapy Services. 2024; Accessed: August 29, 2024. https://www.cms.gov/regulations-and-guidance/guidance/manuals/downloads/bp102c15.pdf.



Evolent Clinical Guideline 1510 for Record Keeping and Documentation Standards: Physical Medicine

Guideline Number: Evolent_CG_1510		
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Original Date: November 2015	Last Revised Date: November 2024	Implementation Date: July 2025

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STATEMENT

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.

Purpose

This guideline will assist the physical therapist, occupational therapist, and/or speech-language pathologist in creating and maintaining complete and appropriate clinical records and documentation.

All recommendations in this guideline reflect practices that are evidence-based and/or supported by broadly accepted clinical specialty standards.

Scope

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.

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.

Special Note

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.

MEDICAL RECORD CONTENT REQUIREMENTS (1,2,3)

General Guidelines

- Documentation should clearly reflect why the skills of a practitioner are needed/the care is <u>medically necessary</u>
- All records (both digital and handwritten) must be legible: the ability of at least two people to read and understand the documents.
- Documentation should be complete and include:
 - o Practitioner's signature and credentials



- Appropriately dated chart entries
- o Patient identifications on each page
- 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.

Evaluation/Re-Evaluation

Initial evaluations and re-evaluations including plan of care (<u>see below</u>) must be performed by a state-licensed PT, OT, SLP, MD, DO or DPM and should document:

- Medical need for a course of treatment through objective findings and subjective self or caregiver reporting
- Pertinent history and general demographics including:
 - Past or current treatment for the same condition
 - Baseline evaluation including current and prior functional status (submit for review)
- Copy of discharge summary including a written letter from the member stating when services ended or a specific reference to the date the member chose 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.
- 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.
 - o Assessment tools used during the evaluation should be:
 - Valid
 - Reliable
 - Relevant to the condition(s) being addressed
 - Supported by the appropriate national therapy best practices guidelines.
 - 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/inability to perform everyday tasks
- 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.
- Medical need for skilled services
- The reason formal testing could not be completed.
- Functional outcome assessment and/or standardized test results to include:
 - Raw scores
 - Standardized scores
 - Score interpretation.
- Detailed clinical observations and 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/SLP)
- Information regarding child's involvement in home and community programs (for Habilitative OT/PT/SLP)

Daily Notes

Should include the following:

- Clear evidence of skilled treatment interventions that cannot be conducted solely by non-skilled personnel.
- Assessment of patient's response or non-response to intervention and plan for subsequent treatment sessions, assessments, or updates
- Any significant, unusual, or unexpected changes in clinical status

Treatment Plan or Plan of Care

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. This includes the use of telehealth rather than on-site treatment.

The plan of care should include the following:

- Meaningful clinical observations
- Patient's response to the evaluation process
- Interpretation of the evaluation results including:
 - o Prognosis for improvement
 - o Recommendations for therapy services amount, frequency, and duration
- Short and long-term goals that are required to achieve targeted outcomes.
 - SMART (Specific, Measurable, Attainable, Realistic, and Time-bound)
 - Detail the type of intervention that must be:



- Skilled treatment interventions, regardless of level of severity of deficit or delay
- Evidence-based
- Chosen to address the targeted goals and/or outcomes.
- Representative of the best practices outlined by the corresponding national organizations.
- 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.
- Amount, duration, and frequency
 - The frequency and duration must be commensurate with:
 - Patient's level of disability
 - Medical and skilled therapy needs
 - Accepted standards of practice
 - Clinical reasoning and current evidence
 - \Box Frequency and duration of skilled services must also be in accordance with the following $^{(4,5,6)}$:
 - ◆ Intense frequencies (≥ 3x/week) require additional documentation and testing to support a medical need (achieve an identified new skill or recover a function with specific, achievable goals within the requested period)
 - Include details on why a higher frequency is more beneficial than a moderate or low frequency.
 - Higher frequencies may be considered when delays are classified as severe (indicated by corresponding objective measures and/or testing guidelines used in the evaluation)
 - More intensive frequencies may be necessary in the acute phase (progressive decline in frequency is expected within a reasonable time)
 - Moderate frequency (2x/week) should be consistent with moderate delays (established by objective measures and/or the general guidelines of formal assessments in the evaluation)
 - ♦ Frequency may be used for ongoing care when documentation supports it as being clinically effective toward achieving the functional goals in the treatment plan within a reasonable time.
 - ◆ 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
 - Visits or units requested must not exceed the frequency and duration supported in the plan of care.
- Linked to functional limitations outlined in the most recent valuation or assessment.



- Additional factors may be considered on a case-by-case basis.
- Expected caregiver involvement in the patient's treatment
- Educational plan, including:
 - Home exercises
 - o Activities of Daily Living (ADL) modifications
 - o Anticipated discharge recommendations including:
 - Education of the member in a home program
 - Primary caregiver education (when applicable)
- 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.
 - o Functional limitations do not support the rate of care requested (stated above)
 - Treatment is provided without a treatment plan, functional goals, or recent, sustained improvement.
- 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 measures
- Updated outcome measure scoring and interpretation of results
- Overall quantified progress towards each goal (including if goal has been met or not met)
- Modification of treatment interventions needed to meet goals.
- Goals updated as appropriate.
- Summary of a patient's response (or lack thereof) to intervention
- Statement (brief) of the prognosis or potential for improvement in functional status
- Updates to the frequency or amount of expected care in preparation for discharge

Note: Treatment must not be focused on returning to activities beyond normal daily living, including but not limited to return to sports, recreational activities, and/or work-specific tasks.

Maintenance Care

Maintenance level of therapy services may be considered when a member requires skilled therapy for ongoing periodic assessments, consultations, and treatment.

- Goals in the plan of care must reflect that care is focused on maintaining the current level of function 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 documentation must clearly demonstrate that the specialized judgement, 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.
- It is expected that evidence will be provided regarding the implementation of a comprehensive home program with indications of compliance by the member to the home program for maximum benefit of therapy.

Lack of Information

Reviewers can determine that claims or 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, and insufficient detail showing clear evidence supporting recent significant progress with treatment, such as lacking baseline/updated objectives and goals, or specific plan of care) may result in 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.

CODING AND STANDARDS

Applicable Lines of Business

\boxtimes	CHIP (Children's Health Insurance Program)
\boxtimes	Commercial
\boxtimes	Exchange/Marketplace
\boxtimes	Medicaid
\boxtimes	Medicare Advantage

BACKGROUND

Medical Necessity (1,2,7)

Medically necessary services are reasonable or necessary services that require the specific training, skills, and knowledge of a physical or occupational therapist and/or speech/language pathologist 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 practitioner.

- 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.
 - Simply because a licensed practitioner furnishes it.
 - If a service can be self-administered or safely and effectively conducted by an unskilled person, without the direct supervision of a practitioner, then it cannot be regarded as a skilled service even though a licensed practitioner rendered the service.
 - The unavailability of a competent person to provide a non-skilled service resulting in the non-skilled service being rendered by a licensed practitioner does not make the service provided a skilled service.
 - They include repetitive activities (exercises, skill drills) which do not require a licensed practitioner's expertise (knowledge, clinical judgment and decisionmaking abilities) and can be learned and performed by the patient or caregiver.
 - o They are activities for general fitness and flexibility, sports-specific training enhancement or general tutoring for improvement in academic performance.

Medically necessary care must be:

- **Contractual** all health care services are determined by the practitioner's contract with the payer and individual health plan benefits.
- Within Scope of Practice all health care services are limited to the scope of practice under all applicable state and national health care boards.
- Within Standard of Practice all health care services must be within the practitioner's generally accepted standard of practice.
- Considerate of Patient Safety all health care services must be delivered in the safest possible manner.
- A 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.
- Considerate of Setting all health care services must be delivered in the least intensive setting.
- Considerate of 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.
- **Supported by Clinical Guidelines** health care services meet all of the Clinical Guidelines of this organization.



POLICY HISTORY

Date	Summary	
November 2024	 This guideline replaces Evolent Clinical Guideline 606-01 for Record Keeping and Documentation: Physical Medicine Updated references 	
December 2023		
December 2023	"Maintenance Section" added	

LEGAL AND COMPLIANCE

Guideline Approval

Committee

Reviewed / Approved by Evolent Specialty Clinical Guideline Review Committee

Disclaimer

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REFERENCES

- 1. Occupational Therapy Practice Framework: Domain and Process—Fourth Edition. Am J Occup Ther. 2020; 74: 7412410010p1 7412410010p87. 10.5014/ajot.2020.74S2001.
- 2. American Speech-Language-Hearing Association. Documentation in health care [Practice Portal]. Accessed: August 29, 2024. https://www.asha.org/practice-portal/professional-issues/documentation-in-health-care/.
- 3. American Physical Therapy Association. APTA Guide to Physical Therapist Practice 4.0. 2023; Accessed: August 29, 2024. https://guide.apta.org.
- 4. Academy of Pediatric Physical Therapy A P T A. Intensity of Service in an Outpatient Setting for Children With Chronic Conditions. 2012; Accessed: August 26, 2024. https://pediatricapta.org/includes/fact-sheets/pdfs/FactSheet IntensityofServiceforChildrenwithChronicConditionsOutpatientSetting.pdf.
- 5. Dannemiller L, Mueller M, Leitner A, Iverson E, Kaplan S. Physical Therapy Management of Children With Developmental Coordination Disorder: An Evidence-Based Clinical Practice Guideline From the Academy of Pediatric Physical Therapy of the American Physical Therapy Association. Pediatric Physical Therapy. 2020; 32:
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- 7. Centers for Medicare and Medicaid Services. Regulations and Guidance Manuals (Internet Only Manuals) Medicare Benefit Policy Manual Chapter 15: Medical and Other Health Services 220.3 Documentation Requirements for Therapy Services. 2024; Accessed: August 29, 2024. https://www.cms.gov/regulations-and-guidance/guidance/manuals/downloads/bp102c15.pdf.



Evolent Clinical Guideline 1501 for Chiropractic Infant Care Policy

Guideline Number: Evolent_CG_1501		
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Original Date: April 2016	Last Revised Date: November 2024	Implementation Date: July 2025

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STATEMENT

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.

Purpose

Support medically necessary, appropriate, and acceptable chiropractic treatment of infants (age: birth to 24 months).

Special Note

The evaluation, diagnosis, and management of infants falls within the scope of chiropractic practice.

NOTE: Chiropractic providers should not engage in unsafe or unproven services as outlined in this policy. There is insufficient evidence that manual therapy (spinal manipulation, extraspinal manipulation, and mobilization) results in improved health outcomes, particularly functional outcomes, related to the treatment of both musculoskeletal and non-musculoskeletal infant conditions. ⁽¹⁾

Scope

This guideline applies to all physical medicine participating network practitioners.

INDICATIONS

ALL of the following apply:

- Therapeutic trial of chiropractic care for the infant patient (2):
 - o In the absence of conclusive evidence, clinical experience and patient/parent preferences must align
 - If the infant patient shows no clinically significant improvement (progress toward measurable goals) after a trial period of chiropractic care, no additional chiropractic care is indicated, and referral may be appropriate
- Manual-based therapy (spinal/extraspinal manipulation and mobilization), active care, and passive therapies have not been shown to improve the health outcomes of spine, extremity-based musculoskeletal conditions, or non-musculoskeletal conditions (childhood immunizations, treatment of infectious diseases, etc.) in infant populations (3)
- There is no contemporary chiropractic consensus demonstrating a general agreement to support the treatment of non-musculoskeletal conditions, (4) such as:
 - Treatment of the common cold
 - o Sinus congestion



- o Allergies
- Sleep disturbances
- Difficulty nursing
- o Infantile colic
- o ADHD
- o Asthma
- Autism
- Cerebral palsy
- o Constipation
- Nocturnal enuresis
- o Otitis media
- Chiropractic infant care for wellness care, well-baby checks, and preventive care are NOT covered
- o The use of maintenance or preventive[±] spinal/extraspinal manipulation

NOTE: This organization has the decisive authority to determine if treatment is medically necessary and appropriate.

CODING AND STANDARDS

Applicable Lines of Business

×	CHIP (Children's Health Insurance Program)
×	Commercial
×	Exchange/Marketplace
×	Medicaid
×	Medicare Advantage

BACKGROUND

[‡]Preventive, defined as prevention of any disease or condition or the promotion and enhancement of health after maximum therapeutic benefit has occurred.

Literature Support

As of August 15, 2023, there is no first-level, evidence-based literature in relation to the effectiveness of manual therapy/manipulation for spinal disorders in the infant (young) population. (4,5)



Infantile Colic

In the American Academy of Family Physicians (AAFP) report on infantile colic, one of the primary levels of treatment is parental reassurance and support because colic is benign. ⁽⁶⁾ Although the AAFP article addresses physical therapies for colic, which included chiropractic and osteopathic manipulation, massage, and acupuncture, there is insufficient evidence to support these therapies. ⁽⁴⁾

Non-musculoskeletal

The American Academy of Pediatrics clinical report on Pediatric Integrative Medicine corroborates there is a lack of quality evidence to support the effectiveness of spinal manipulation for non-musculoskeletal conditions in infants and children in which the risks of adverse events may be the highest because of immature stability of the spine or high-velocity extension and rotational spinal manipulation. (3)

Musculoskeletal

No high-quality methodological 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	
November 2024	This guideline replaces Evolent_CG_611 Chiropractic Infant Care Policy	
	CPT Codes removed from the Indications section. The CPT Codes section in Coding was also removed	
	 Editorial changes to match the formatting and layout of the Evolent template 	
	Edited the 'Infantile Colic' section of the Background to make it more concise	
	Updated references	
December 2023	Editorial changes - sections moved/updated for better reading flow	
	Updated references	



LEGAL AND COMPLIANCE

Guideline Approval

Committee

Reviewed / Approved by Evolent Specialty Clinical Guideline Review Committee

Disclaimer

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HMSA Clinical Guideline 1509 for Record Keeping and Documentation Standards: Chiropractic Care

Administered by Evolent

Guideline Number:			
HMSA_CG_1509	HMSA_CG_1509		
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Original Date:	Last Revised Date	Last Reviewed Date	Implementation
	(by HMSA):	(by Evolent):	Date:
July 2025	July 2025	July 2025	July 2025

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STATEMENT

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.

Special Note

HMSA Coverage Limitations

- Chiropractic treatment is not covered when rendered for non-neuromusculoskeletal
 conditions because such treatment is not included in the chiropractic scope of
 practice in the state of Hawaii. However, because patients may present to
 chiropractors with non-spinal and non-neuromusculoskeletal conditions that the
 chiropractor must evaluate to determine an appropriate medical referral. Coverage
 for initial visit may be covered.
- Maintenance care is not covered. Maintenance care is defined as treatment that
 preserves the patient's pre-incident level of function and prevent regression of that
 function. Maintenance begins when the therapeutic goals of a treatment plan have
 been achieved or when no additional functional progress is apparent.
- Services outside the chiropractor scope of practice listed in HRS: § 442-1 are not covered, including but not limited to: lomilomi and massage therapy.

Purpose

This guideline will assist the chiropractor in creating and maintaining complete and appropriate clinical records and documentation.

All recommendations in this guideline reflect practices that are evidence-based and/or supported by broadly accepted clinical specialty standards.

MEDICAL RECORD CONTENT REQUIREMENTS

General Guidelines (1,2)

- Documentation should clearly reflect why the skills of a licensed chiropractor are needed/the care is <u>medically necessary</u>
- All records (both digital and handwritten) must be legible.
 - o 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 must also contain:
 - o The patient's name or ID number
 - The subjective complaint(s)
 - o Objective findings, assessment



- Diagnosis, treatment/ancillary diagnostic studies performed.
- Any recommendations, instructions, or patient education
- All chart entries must be dated with the month, day, and year.
- Handwritten records
 - o In chronological order and in permanent ink with original signatures
- Electronic entries
 - Use appropriate security and confidentiality provisions.
- Patient demographics including all of the following:
 - Name
 - Address
 - Telephone numbers (home and work)
 - Gender
 - Date of birth
 - o Occupation
 - Marital status
- Working diagnosis(es) or condition description similar to the appropriate ICD code
 - If the ICD code is not applicable/allowed, it must be documented and consistent with the associated findings.
- Reason for the encounter or referral (i.e., presenting complaint(s))
- 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
 - Diagnostic studies
 - Laboratory findings
 - Consultations
 - Reports and correspondence related to treating chiropractor's diagnostic studies
 - Laboratory findings
 - Consultations including
 - Rationale for the service
 - Rationale for consult and findings
 - Conclusions
 - Recommendations
- Copy of discharge 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.
- 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 (1,2)

The evaluation documentation must include:

- Support the medical need for a course of treatment through:
 - Objective findings
 - o Detailed clinical observations
 - Subjective self-reporting
- Patient's prior medical, familial, and social history
- Baseline evaluation
 - Current and prior functional status (functional mobility and ADL deficits)
- Systems review consistent with the nature of the complaint(s) and relevant historical information
- Objective measures and/or standardized orthopedic and neurological testing demonstrating a decline in functional status
 - 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
- 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
 - Medical need for skilled services
 - The reason formal testing could not be completed
- Functional outcome assessment and/or standardized test results with:
 - o Raw scores
 - Standardized scores
 - Score interpretations



Prognosis and rehab potential

Treatment Plan/Plan of Care (2,3)

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

NOTE: Treatment must not be focused on returning to activities beyond normal daily living.

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.

Plan of care elements

- The patient's age and date of birth
- Date of evaluation
- Medical history and background
- All diagnoses related to the patient's condition
- Contraindications to treatment
- 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
- Patient's response to the evaluation process and interpretation of the evaluation results
- Prognosis for improvement
- Recommendations for the amount, frequency, and duration of services must:
 - Include what is required to achieve targeted outcomes
 - o Be commensurate with the patient's level of disability
 - Demonstrate accepted standards of practice
 - Reflect clinical reasoning and current evidence
 - Not request visits that exceed the frequency and duration supported in the plan of care
 - Initial plan of care for a musculoskeletal condition should not exceed 4 weeks
- Patient-specific functional goals that are measurable, attainable, time-specific and sustainable
- Specific therapeutic interventions
- Predicted level of improvement in function (prognosis)
- Specific discharge plan



The plan of care should be reviewed at intervals appropriate to the patient and in accordance with state and third-party requirements. If a plan of care must be updated or altered, documentation must list all changes/updates, including but not limited to:

- New time frame for current treatment period
- Total number of visits from start of care
- Change in objective outcome measures and standardized testing compared to baseline and/or most recent re-assessment
- 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
- 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
- Updated intervention and modality selections
 - Evidence-based and chosen to address the targeted goals
- Educational plan to include
 - o Home exercises
 - o ADL modifications
 - Self-management teaching
- Changed discharge recommendations (including education of the member in a home program)
- Date and signature of treating chiropractor

Daily Treatment Note (3)

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
- Changes in clinical status (significant, unusual, or unexpected)

Re-evaluation

Re-evaluations should not be routine or recurring; an established patient evaluation is indicated if any of the following apply:



- Patient presents with a new condition
- 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
- 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
- Reported condition was acute, sub-acute, or chronic at the onset of care
- Exacerbation or significant flare-up (if applicable)
- Condition is trauma-related, insidious onset, or repetitive/overuse injuries as a result of activities of daily living
- Date of onset and mechanism of onset is specified
- History of the condition
- Interim history for recurrent episodes
- Pain (level, intensity, and frequency)
- Measurable and functional treatment goals are:
 - o Appropriate
 - Time-specific
 - o Monitored



- Outcome Assessment Tools
 - Utilized at pre-determined intervals
 - 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
 - o Minimum detectable change (MDC)
 - o And/Or
 - Minimum clinically important change (MCIC) requirements
- All services billed meet CPT® coding requirements and supported by:
 - Subjective complaints
 - Objective findings
 - o Diagnoses
 - Treatment performed
 - Meet the requirements according to this organization's Clinical Guidelines
- Demonstrated 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 to patient on an "as needed" 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.



CODING AND STANDARDS

Applicable Lines of Business

\boxtimes	CHIP (Children's Health Insurance Program)
	Commercial
\boxtimes	Exchange/Marketplace
	Medicaid
\boxtimes	Medicare Advantage

BACKGROUND

Medical Necessity

Medically necessary services are 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
 - Simply 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.
 - The unavailability of a competent person to provide a non-skilled service resulting in the non-skilled service being rendered by a chiropractor does not make the service provided a skilled service
 - They 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
 - They are activities for general fitness, flexibility, sports-specific training enhancement or general tutoring for improvement in academic performance

Medically necessary care must be:

- **Contractual** all health care services are determined by the practitioner's contract with the payer and individual health plan benefits.
- Within Scope of Practice all health care services are limited to the scope of practice under all applicable state and national health care boards.



- Within Standard of Practice all health care services must be within the practitioner's generally accepted standard of practice.
- Considerate of Patient Safety all health care services must be delivered in the safest possible manner
- A 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
- Considerate of Setting all health care services must be delivered in the least intensive setting
- Considerate of 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
- Supported by Clinical Guidelines
 – health care services meet all of the Clinical Guidelines of this organization.

Medical History

The Medical History includes all of the following:

- The History of Present Illness (HPI)
 - o 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)
 - o 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
 - includes marital status, living conditions, education/occupation, alcohol/drug use, sexual history

Definitions

Physical Examination (PE): 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.

POLICY HISTORY

Date	Summary
July 2025	Health Plan Specific guideline created for HMSA with health- plan requested language in the Special Note

LEGAL AND COMPLIANCE

Guideline Approval

Committee

Reviewed / Approved by Evolent Specialty Clinical Guideline Review Committee

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Evolent Clinical Guideline 1507 for Passive Treatment

Guideline Number:

Evolent_CG_1507

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STATEMENT

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.

Purpose

This organization does not recognize the use of multiple passive treatments for the care of musculoskeletal pain as 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.

All recommendations in this guideline reflect practices that are evidence-based and/or supported by broadly accepted clinical specialty standards.

Scope

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

INDICATIONS

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 for which the service will be provided, goals for each service, and a time component, if indicated.

Appropriate Use

Clinically Appropriate Use of Passive Treatment

- 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
 - o Most studies show the duration of treatment effectiveness was typically reported as short (2 weeks to 2 months).
- 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)
 - Most international guidelines recommend these interventions should only be reservedly used based upon individual circumstances and not as a principal



component of a treatment regime.

 Used for a particular condition for which there is an evidence-basis of significant benefit.

Clinically Inappropriate Use of Passive Treatment

- When patient safety is jeopardized by the application of the modality
- When 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.
 - 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.
- Used as the primary or sole therapy.
- More than two passive treatments are 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 (CPT codes: 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.

Procedures and Modalities

Thermotherapy/Cryotherapy

The superficial or deep application of heat or cold.

- Superficial
 - o Hot/cold packs
 - o Paraffin bath
 - o Whirlpool
- Deep
 - Diathermy
 - Microwave
 - Ultrasound (US)

NOTE: Thermal therapy has been found to be most successful in the short-term relief of musculoskeletal pain but is also often used in conjunction with other therapies to improve outcomes. ^(1,2)

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NOTE: Ultrasound therapy is used as both thermal therapy and mechanical therapy ⁽³⁾ and may provide short-term pain relief for knee osteoarthritis. ^(4,5)

Light Therapy (aka Phototherapy)

Light concentrated in a narrow beam to excite cells in local tissues.

- Ultraviolet
- Infrared
- Laser therapy
 - o Low level
 - o High level

NOTE: Ultraviolet therapy is primarily used to treat skin disorders and promote wound healing.

NOTE: Both low (including infrared) and high level laser therapy have been shown effective in reducing pain and as adjuncts to other physical therapy modalities. (4,6,7)

Electrical Stimulation Therapy

- Administration of an electrical current to a specific, localized body site.
- Volt
 - High
 - o Low
- Interferential current (IFC)
- Transcutaneous electrical nerve stimulation (TENS)
- Neuromuscular electrical stimulation (NMES)

NOTE: IFC and TENS have consistently been found to reduce pain during and shortly after application, helping facilitate other therapies and/or improving outcomes. ^(6,9)

Mechanical Therapy

Mechanically assisted and often sustained pull of the spine or limb

Traction

NOTE: Lumbar traction has been shown to be effective in relieving low back pain and lumbar radiculopathy. (10,11)

NOTE: Cervical traction may offer some short-term pain relief for neck pain and cervical radiculopathy. (12,13)

Therapeutic Massage and Manual Therapy

Includes but not limited to:

- Active Release Technique
- Trigger point therapy
- Myofascial release

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Evolent Clinical Guideline 1507 for Passive Treatment



- Mobilization/manipulation
- Manual lymphatic drainage
- Manual traction

NOTE: A range of manual therapies have been found to be effective in treating tension-type headaches. (14,15)

NOTE: Manual therapies can decrease pain, increase range of motion, and improve functionality in a range of musculoskeletal conditions, including osteoarthritis. (4,16,17)

CODING AND STANDARDS

Applicable Lines of Business

\boxtimes	CHIP (Children's Health Insurance Program)
\boxtimes	Commercial
\boxtimes	Exchange/Marketplace
\boxtimes	Medicaid
	Medicare Advantage

BACKGROUND

Definitions

<u>Modality</u>: 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.

<u>Multiple Modalities</u>: the use of and/or billing of two or more physical medicine modalities each visit or during the same session to the same region.

<u>Passive Treatment</u>: treatment that is applied by the provider or in a clinical setting and does not involve active participation by the patient.

<u>Procedure</u>: a service provided to increase the functional abilities in self-care, mobility, or safety.



POLICY HISTORY

Date	Summary	
November 2024	This guideline replaces Evolent Clinical Guideline 604 for Passive Treatment	
	Updated references	
	Added knee osteoarthritis to ultrasound section	
December 2023	Clinical guidance was reorganized to emphasize indications rather than contraindications	

LEGAL AND COMPLIANCE

Guideline Approval

Committee

Reviewed / Approved by Evolent Specialty Clinical Guideline Review Committee

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Evolent Clinical Guideline 1503 for Experimental, Unproven, or Investigational Services

Guideline Number: Evolent_CG_1503		
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STATEMENT

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.

Purpose

To provide a listing of procedures or services considered experimental, investigational, or unproven provided by any physical medicine practitioner[±].

Special Note

This policy lists the procedures considered experimental, or investigational provided by any physical medicine practitioner[±].

NOTE: Services listed in the policy are not eligible for reimbursement.

Coverage

If there is inconsistency between this medical policy and the terms of an enrollee's benefit plan, the terms of the enrollee's benefit plan supersede this policy.

NOTE: Coverage is subject to the terms of an enrollee's benefit plan

SERVICES

Defined

Experimental and investigational services (treatment, service, procedure, supply, device, or drug) are not recognized as standard clinical care for the condition (disease, illness, or injury) when scientific evidence to support its use is insufficient.

A service, procedure, or supply includes but is not limited to:

- Diagnostic service
- Treatment
- Facility
- Equipment or device

NOTE: This organization will determine whether a service, procedure, or supply is considered experimental and investigational, based upon reliable scientific methodology published in credible peer-reviewed journals or expert opinion from national and international professional medical organizations in the absence of definitive data.

Criteria

A service is considered experimental/investigation if **ANY** of the following criteria is met:

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Evolent Clinical Guideline 1503 for Experimental, Unproven, or Investigational Services



- A service, treatment, procedure, supply, device, or drug requiring appropriate government regulatory bodies approval does **NOT** have final approval (e.g., the Food and Drug Administration)
 - Restricted market approval for use in the treatment of a specified condition (not substituted for final approval)
 - o Interim step in the regulatory process (not substituted for final approval)
- Insufficient or inconclusive evidence of the service, procedure, or supply
 - To evaluate the therapeutic value
 - o On the beneficial effect on health outcomes
 - Is not as beneficial as an established alternative
 - When used in a non-investigational setting the service, procedure, or supply has a beneficial effect on health outcomes as any established alternatives

Experimental and Investigational Services

Experimental and investigational services listing (non-exclusive list):

- Advanced BioStructural Correction™ (ABC™)
- Alphabiotics
- Applied Kinesiology (including subfields)
- Applied Spinal Biomechanical Engineering
- Bio-Energetic Synchronization Technique (B.E.S.T)
- Blood Flow Restriction Training
- Chiropractic Biophysics (CBP, Clinical Biomechanics of Posture, CBP Mirror Image Technique)
- Chiropractic services directed at controlling progression and/or reducing scoliosis, including but not limited to the SpineCor brace and CLEAR scoliosis treatment
- Coccygeal Meningeal Stress Fixation
- Cold Laser Therapy
- Computerized muscle testing or analysis
- Cupping
- Craniosacral Therapy (CST, including the Upledger Technique)
- Directional Non-force Technique
- Dry Needling
- Hako-Med electrotherapy (horizontal electrotherapy)
- High-density surface electromyography (HD-sEMG), surface scanning EMG, paraspinal surface EMG, or macro EMG Hippotherapy (e.g., evaluating low back pain, thoracolumbar segmental abnormalities, soft tissue injury, intervertebral disc disease, nerve root irritation, or scoliosis)
- Impulse adjusting instrument



- Intersegmental traction and Autotraction
- Kinesio taping (Elastic Therapeutic Taping)
- Live Cell Analysis or hair analysis
- Manipulation under Anesthesia (MUA)
- Moire Contourographic Analysis
- Nambudripad's Allergy Elimination Technique (NAET)/ other Allergy Testing
- National Upper Cervical Chiropractic Association (NUCCA technique)/Grostic technique
- Network Chiropractic, Neuro Emotional Technique (NET)
- Neural Organizational Technique, Contact Reflex Analysis (CRA), Whole System Scan
- Neurocalometer, Nervo-Scope, Nerve Conduction Velocity, Surface EMG, Paraspinal Electromyography, Spinoscopy or other nerve conduction testing for non-specific neck and back pain
- Neurophysiologic Pain Profile (NPP), spine matrix scan (lumbar matrix scan)
- Nimmo Receptor-Tonus method
- Pettibon, including, but not limited to wobble chair/board treatment and posture pump
- Preventive Care, Corrective Care (chiropractic services)
- Pro-Adjuster
- Sacro Occipital Technique, Neurocranial Restructuring (NCR), Cranial Manipulation
- Sound Assisted Soft Tissue mobilization
- Spinal Diagnostic Ultrasound
- Repeat imaging to determine the progress of conservative treatment
- Thermography
- Treatment for brachioradial pruritis
- Vascular Studies, including, but not limited to, Doppler ultrasound analysis and plethysmography
- VAX-D, 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), 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

Services Exceptions (Possibly Covered Under Another Service)

Whole body vibration as a treatment for low back pain (LBP) evidence remains



equivocal

 Low level laser therapy could be an effective method for relieving pain in non-specific chronic low back pain (1)

NOTE: No significant treatment effect was identified for disability scores or spinal range of motion outcomes. Laser therapy combined with exercise provides better short-term relief of low back pain than either therapy alone. ⁽²⁾ No short-term benefit of laser therapy when compared with exercise alone. ⁽²⁾

Plethysmography

- <u>Plethysmography</u> is one diagnostic modality for the conditions listed below or as an initial evaluation to determine the need for venography or arteriography
 - o Chronic venous disease (3,4)
 - o Arterial occlusive disease (5)
 - Evaluating total lung capacity and residual volume (Body Plethysmography/Pulmonary Function Test) (6)

NOTE: 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.

Election of Services by Member

- If an experimental, unproven, or investigational service are to be provided, the
 practitioner will inform the member, in writing, that such services will be the member's
 responsibility
 - No 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 a more accurate diagnosis, nor do they result in an improved clinical outcome
- For member exclusions or limitations refer to the enrollee's Certificate of Coverage or Summary Plan Description

Future Considerations

Removal of a service from the Experimental and Investigations Policy

- A review of the current literature will be evaluated annually to determine if there is additional evidence in support of any of the services listed under this policy (governmental regulatory bodies approval and scientific evidence)
- Scientific evidence must demonstrate the final conclusions pertaining to a treatment are based upon sound scientific study methodology published in credible, peer reviewed journals following a hierarchy of reliable evidence is used:
 - Systematic reviews or Meta analyses of randomized controlled trials
 - o Technology assessments
 - Randomized Controlled Trials
 - Cohort studies



- Case-Control studies
- National and International Professional Medical Societies consensus (in absence of definitive scientific data)

NOTE: reliable evidence comes from well designed, high quality, double-blinded studies and not from personal professional opinions or personal choice for the standard of practice

- Services must be proven safe and effective:
 - Safety
 - Is the potential benefit superior to the potential harm
 - Health Outcomes
 - Superior or comparable to the established alternatives
 - o Patient Management
 - Does the service improve clinical decision making
 - o Clinical Performance
 - Is the reliability and predictive value of the service equal or superior to the current gold standard for the service
 - Cost-effectiveness
 - Is the service equal to or lower cost than established treatments that produce similar outcomes

NOTE: 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.

CODING AND STANDARDS

Applicable Lines of Business

×	CHIP (Children's Health Insurance Program)
×	Commercial
×	Exchange/Marketplace
×	Medicaid
⊠	Medicare Advantage



BACKGROUND

Health Care Providers

[‡]A qualified licensed health care providers (chiropractors, physical therapists, occupational therapists, speech language pathologist, physician assistants, speech language pathologist assistants, physical therapist assistants, and occupational therapy assistants) by education, training, and licensure/regulation performs a professional service within his/her scope of practice and reports to health professional boards.

POLICY HISTORY

Date	Summary	
November 2024	This guideline replaces Evolent_CG_601 Experimental, Unproven, or Investigational Services	
	Removed the CPT Codes section within Coding	
	Editorial changes to match the formatting and layout of the Evolent template	
	Corrected 'Resistance' to 'Restriction' for Blood Flow Restriction Training in the Indications section	
	Clarified language regarding Plethysmography within the "Service Exceptions" section	
December 2023	Removed; Services Exceptions – Ultrasound: as ultrasound is not applicable to therapy services	
	 Editorial changes-sections adjusted/moved for better reading flow 	
	Updated References	

LEGAL AND COMPLIANCE

Guideline Approval

Committee

Reviewed / Approved by Evolent Specialty Clinical Guideline Review Committee

Disclaimer

Evolent Clinical Guidelines do not constitute medical advice. Treating health care professionals are solely responsible for diagnosis, treatment, and medical advice. Evolent uses Clinical Guidelines in accordance with its contractual obligations to provide utilization management. Coverage for services varies for individual members according to the terms of their health care coverage or government program. Individual members' health care



coverage may not utilize some Evolent Clinical Guidelines. A list of procedure codes, services or drugs may not be all inclusive and does not imply that a service or drug is a covered or non-covered service or drug. Evolent reserves the right to review and update this Clinical Guideline in its sole discretion. Notice of any changes shall be provided as required by applicable provider agreements and laws or regulations. Members should contact their Plan customer service representative for specific coverage information.



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Evolent Clinical Guideline 1504 for Measurable Progressive Improvement

Guideline Number:

Evolent_CG_1504

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Last Revised Date:
November 2024

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STATEMENT

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.

Purpose

This guideline provides 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.

All recommendations in this guideline reflect practices that are evidence-based and/or supported by broadly accepted clinical specialty standards.

Special Note

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

MEASURABLE IMPROVEMENT

Defined

Meaningful clinical changes are calculated outcome measures using a standardized assessment tool. Using standardized assessment tools in the management of neuromusculoskeletal disorders follows Physical Medicines professional standards. These include:

- Minimal Clinically Important Change (MCIC)
- Minimal Clinically Important Differences (MCID)
- Minimal Detectable Change (MDC)
- Minimal Important Change (MIC)
- Maximum Therapeutic Benefit (MTB)
- Smallest Detectable Change (SDC)
- Standard Error of Measurement (SEM)
- Small Meaningful Change (SMC)
- Smallest Real Change (SRC)



Scope

In determining meaningful progress toward goals (MCIC and MTB) the record must include documented relevant standardized outcome assessments. The calculated outcome measures can be used to set goals and determine treatment effectiveness. Progress towards goals should be assessed at predetermined time periods and supported by anticipated meaningful clinical change based on the treatment plan goals, e.g.:

- 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)
- This organization requires all practitioner records must evaluate and document whether treatment is resulting in progressive and sustained improvement, including 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
- Measured by one or more of the below methods for each anatomic region (listed below in [±]Measurable Improvement Acceptable Thresholds) (2)
- If no functional tool is available for the patient's condition it is expected the practitioner will develop specific, measurable, and functional goals

Acceptable Thresholds

5 Times Sit to Stand Test (5XSTS) (3)

- Older Adults: 5 repetitions of this test exceeding the following can be considered to have worse than average performance
 - o 11.4 s (60 to 69 years)
 - o 12.6 s (70 to 79 years)
 - o 14.8 s (80 to 89 years)
- MCID
 - Vestibular Disorders = 2.3 seconds
- MDC
 - Vestibular Disorders = 3.6 to 4.2 seconds

6-Minute Walk Test (6MWT) for Older Adults

- MDC
 - o Alzheimer's Disease: 33.5 m (110 feet) (4)
 - Hip Osteoarthritis or knee osteoarthritis that later received a total joint replacement: 61.34 m ⁽⁵⁾
 - Huntington's Disease chronic progressive (2)
 - Premanifest = 39.22 m
 - Manifest = 86.57 m



- Early-stage = 56.6 m
- Middle-stage = 126.14 m
- Late-stage = 70.65 m
- Multiple Sclerosis chronic progressive: 88 m ⁽²⁾
- o Multiple Sclerosis chronic progressive = 20% (2)
- o Older Adults: 58.21 m (4)
- o Parkinson's Disease: 82 m (2,4)
- o Stroke chronic: 34 37 m or 13% change (4)
- o Stroke subacute: 61 m

MIC

- Multiple Sclerosis chronic progressive (mild to severe): 21.56 m (patient anchor) (2)
- Multiple Sclerosis chronic progressive (mild to severe): 9.06 m (clinician anchor) (2)
- Multiple Sclerosis chronic progressive (deterioration): -53.35 m (patient anchor)
- Multiple Sclerosis chronic progressive (deterioration): -55.06 m (clinician anchor) (2)

SEM

- Multiple Sclerosis chronic progressive: 32 m ⁽²⁾
- o Stroke subacute: 22 m (2)
- o Stroke chronic: 12 18 m (4)

SMC

- Older adults with limited mobility: 20 m (66 feet) (4)
- Older adults with stroke: 22 m (72 feet)
- Stroke subacute: 21 m (anchor stairs) (2)
- Stroke subacute: 54 m (anchor-walk block) (2)

• SRCindividual

- Multiple Sclerosis chronic progressive (mild to severe): 67.22 m (patient anchor) (2)
- o Multiple Sclerosis chronic progressive (mild to severe): 68.32 m (clinician anchor) (2)

10 Meter Walk Test (10MWT) (6)

- Normative Values (m/s) Healthy Adults
 - Men/Women (20s) = 1.358/1.341
 - Men/Women (30s) = 1.433/1.337
 - o Men/Women (40s) = 1.434/1.390

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- Men/Women (50s) = 1.433/1.313
- o Men/Women (60s) = 1.339/1.241
- o Men/Women (70s) = 1.262/1.132
- o Men/Women (80/90s) = 0.968/0.943

MDC

- o Huntington's Disease
 - Pre-manifest, comfortable = 0.23 m/s
 - Manifest, comfortable = 0.34 m/s
 - Early-stage, comfortable = 0.20 m/s
 - Middle-stage, comfortable = 0.46 m/s
 - Late-stage, comfortable = 0.29 m/s
- o Multiple Sclerosis = 0.26 m/s
- Parkinson's Disease (comfortable) = 0.18 m/s
- Parkinson's Disease (fast) = 0.25 m/s
- Spinal Cord Injury (incomplete < 12 months) = 0.13 m/s
- o Stroke (acute) = 0.11 m/s
- Stroke (chronic > 6 months, comfortable) = 0.18 m/s
- O Stroke (chronic > 6 months, fast) = 0.13 m/s
- MCID
 - o Stroke (subacute) = 0.16 m/s

Activities of Daily Living Scale of the Knee Outcome Survey

- MCID
 - \circ = 7.1% (7)
- MDC
 - \circ = 2.23 (8)

Activity-Specific Balance Confidence Scale (ABC)

- MCID
 - o Vestibular Disorders = 18.1% (9)
- MDC
 - o Parkinson's Disease = 11 13% (10,11)
 - o Parkinson's Disease chronic progressive = 13 (2)
 - o Cerebral Vascular Accident = 14%
- SEM
 - o Parkinson's Disease chronic progressive = 11% (2)



- o Parkinson's Disease = 4.01 (10)
- o Stroke acute and chronic = 5.05 6.81 (10)
- o Older adults = 1.2 (10)
- SMC
 - o Older adults = 7 points

Berg Balance Scale (BBS)

- MIC (2)
 - Multiple Sclerosis: deterioration (clinician anchor) = -0.60
 - Multiple Sclerosis: deterioration (patient anchor) = -1.41
- MCID (12)
 - o Subacute stroke (assisted walking): 5 points
 - o Subacute stroke (unassisted walking): 4 points
- MDC
 - $\circ = 6.2 6.5 \text{ points}^{(13)}$
 - o Alzheimer's Disease and Progressive Dementia = 1.92 (14)
 - o Huntington's Disease (2)
 - Chronic progressive premanifest = 1
 - Chronic progressive manifest = 5
 - Chronic progressive early-stage = 4
 - Chronic progressive middle-stage = 5
 - Chronic progressive late-stage = 5
 - o Older adults = 8 10.5 points (14,15)
 - o Parkinson's Disease = 5 points (2)
 - o Stroke (acute) = $6 (90\%)^{(2)}$
 - o Stroke (acute) = $7 (95\%)^{(2)}$
 - o Stroke (chronic) = 2.7 points (14)
 - o Stroke (chronic/stable) = 4.66 6.7 (2)
- SEM
 - Alzheimer's Disease and Progressive Dementia = 0.97 (14)
 - o Stroke (acute) = $2.49^{(2)}$
 - o Stroke (chronic/stable) = $1.49 2.4^{(2)}$
 - o Traumatic Brain Injury = 1.65 (16)

Bournemouth - Back Questionnaire (17)

Acute: change of 26 points



Chronic: change of 18 points

NOTE: 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 (18)

• A change of 13 points or 36% is considered clinically significant improvement

NOTE: 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) (19)

- MCID
 - Children aged 3-6 years with intellectual disability
 - = 6.5 (BOTTM-2-SF Standard Scores)
 - Children aged 4-21 years with intellectual disability
 - = 6.5 (aged 4-12 years) (BOTTM-2-SF standard scores)
 - = 7.4 (aged 13-21 years) (BOTTM-2-SF standard scores)
 - Balance subtest: children with Cerebral Palsy = 2.54 (20)
- MDC
 - Children aged 3-6 years with intellectual disability
 - = 7.4 (BOTTM-2-SF Standard Scores)
 - Children aged 4-21 years with intellectual disability
 - = 4.2 (aged 4-12 years) (standard scores)
 - = 7.4 (aged 13-21 years) (standard scores)
 - Children aged 7-10 with fetal alcohol syndrome
 - = 6.1 (BOT™-2-SF Raw scores)
 - Balance subtest: children with Cerebral Palsy = 9.61
- SEM
 - Children aged 3-6 years with intellectual disability
 - = 1.6 (BOTTM-2-SF standard scores)
 - Children aged 7 9 years with fetal alcohol disorders= 2.2 (BOT™-2-SF raw score) / 2.1 (BOT™-2-SF standard score)
 - Balance subtest in children with Cerebral Palsy = 0.70

Disability of Arm, Shoulder, and Hand (DASH)

- MCID (21)
 - Elbow Arthroplasty (much worse or much better) = 19 points
 - Elbow Arthroplasty (somewhat better or somewhat worse) = 10 points



- Elbow Arthroplasty (no change) = -3 points
- Musculoskeletal Upper Extremity (Adults) = 10.2

MDC

- Humeral Joint Pain and Fractures = 16.1 (DASH) (21)
- Musculoskeletal Upper Extremity (Adults) = 10.7 12.2 (90% CI) (21)
- Musculoskeletal Upper Extremity (Adults) = 12.75 (95%CI) (21)
- o Shoulder = 10.7% (90%CI) (22)
- Shoulder = 12.75% (95%CI) (22)

SEM

- Humeral Joint Pain and Fractures = 5.82 (DASH) (21)
- Musculoskeletal Upper Extremity (Adults)= 4.6 5.22 (21)
- o Osteoarthritis = 2.27 (DASH 0-3*) (21,23)
- o Osteoarthritis = 3.26 (DASH 0-6*) (21,23)
- o Osteoarthritis = 4.49 (DASH 0-12* Osteoarthritis) (21,23)

NOTE: *Paired differences of the DASH score; DASH 0 is mean score preoperative, DASH 3 is mean score at 3 months, DASH 6 is mean score at 6 months, and DASH 12 is mean score at 12 months.

Disability of Arm, Shoulder, and Hand (QuickDASH) (24)

- MCID
 - Upper Extremity (whole) = 8 points
- MDC
 - o = 11 17.2 points (90%CI)
 - \circ = 20.4 points (95%CI)
- SEM
 - o = 6.43 (very much improved)
 - \circ = 3.26 (much improved)
 - o = 3.37 (minimally improved)
 - \circ = 10.22 (no change)

Dizziness Handicap Inventory (DHI)

- MCID
 - Benign Paroxysmal Positional Vertigo = decrease from 18.05 at the first day to 9.54 at 30 days (25)
 - Vestibular Disorders = change of 18 points (95% CI, pretreatment and posttreatment scores difference) (25,26)
- MDC



- o Multiple Sclerosis = 22.50 (25)
- o Vestibular Disorders = 17.18 points (26)
- SEM
 - o Vestibular Disorders = 6.2 (25,26)

Dynamic Gait Index (DGI)

- MDC
 - o Multiple Sclerosis = $4.19 5.54^{(27)}$
 - o Stroke = 4 points (27)
 - o Stroke (change) = 16.6% (27)
 - o Stroke (chronic) = 2.6 points (27)
 - o Parkinson's Disease = 13.3% (27,28)
 - o Parkinson's Disease and Older Adults = 2.9 points (27,28)
 - o Vestibular Disorders = 3.2 points (27,29)
- SEM
 - o Older Adults = 1.04 points (27)
 - Multiple Sclerosis (inter-rater reliability) = 1.51 points (27)
 - o Multiple Sclerosis (intra-rater reliability) = 2.00 points (27)
 - o Stroke (chronic) = $0.71^{(27)}$
 - o Stroke (inter-rater reliability) = 0.94 (30)
 - o Stroke (test-retest condition) = 0.97 (30)
 - Vestibular Disorders = 2.8 points (27,29)

Falls Self Efficacy Scale/Falls Efficacy Scale-International (FES-I) (31)

- MDC
 - Multiple Sclerosis = 0.52 points
 - Older Adult (Hip fracture) = 17.7 points (32)
 - o Vestibular Disorders = 8.2 points
- SEM
 - Multiple Sclerosis = 0.19 points
 - Oder Adult (Hip Fracture) = 6.4 points (32)
 - Vestibular Disorders = 3.0 points

Foot and Ankle Ability Measures (FAAM) (33,34)

- MCID
 - Activities of Daily Living (subscale) = 8% points
 - Sport (subscale) = 9% points

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- MDC
 - Activities of Daily Living (subscale 95% CI) = 5.7
 - o Sports (subscale 95% CI) = 12.3
- SEM
 - o Activities of Daily Living (subscale) = 2.1
 - o Sports (subscale) = 4.5

Fear Avoidance Belief Questionnaire (FABQ)

- MCIC
 - o Arthroscopic subacromial decompression (following) = -5.0 (35)
- MCID (36)
 - Lower Back Pain = 13 points
 - Physical Activity (Pelvic Girdle Pain) = 25%
- MDC
 - o Low back pain = -5.4
 - Physical Activity (Pelvic Girdle Pain) = 6.1 (36)
 - o Physical Activity (Subscale) = 12 points (37)
 - Physical Activity (Worker UE injury) = 8 points (change scores equivalent to 30-33% of scale) (36)
 - o Work (Subscale) = 9 points (37)
- SEM
 - Physical Activity (Pelvic Girdle Pain) = 2.20 (36)

Functional Gait Assessment (FGA) (38)

- MCID
 - Older Adults = 4 points (from interim to end of care) (39)
 - Vestibular Disorders = 4 points (9)
 - Vestibular Disorders = 18.1%
- MDC
 - o Parkinson's Disease = 4 points (39)
 - o Stroke (acute and chronic) = 4.2 (39)
 - Stroke (acute and chronic) = 14.1% (39)
 - Vestibular Disorders (acute) = 6 points (95% CI) (2)
- SEM
 - o Stroke = 1.52 (39)



Functional Rating Index (FRI) (40)

- MCIC
 - Spinal musculoskeletal system = 10% absolute change
- MCID
 - Spinal musculoskeletal system = 8.4%
- MDC
 - Spinal musculoskeletal system = 15%

NOTES:

- Acute and subacute conditions: recommended the FRI be used at baseline and every 1 week or 3 visits thereafter
- Chronic conditions: recommended 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

Functional Status (FS) Measure or FOTO (41,42)

- The MCII (Minimally Clinically Important Improvement) and MDC are stated on the assessment report
 - For significant, minimal improvement, the patient status should increase by the MDC value

NOTE: FOTO summary report is available upon request

Gait Speed for Adults (43-45)

- MCID
 - Joint pain and fractures = 0.1 m/s
 - o Older Adults = 0.05 0.12 m/s
 - Older Adults with Heart Failure = 0.05 0.12 m/s
 - Chronic Obstructive Pulmonary Disease = 0.11 m/s (anchored against ISW)
 - Chronic Obstructive Pulmonary Disease = 0.08 m/s (anchored against self-reported improvement)
 - o Stroke = 0.1 m/s
 - o Vestibular Disorders = 0.09 m/s (9)
- MDC
 - o Heart Failure = 0.05 m/s
 - Joint pain and fractures = 0.08 m/s
 - o Older Adults = 0.05 m/s
 - Pulmonary Diseases (Chronic Obstructive Pulmonary Disease) = 0.11 m/s (95% CI)



- Meaningful change for those with stroke undergoing rehab = 0.175 m/s
- SEM
 - Pulmonary Diseases (Chronic Obstructive Pulmonary Disease) = 1.14% (Interobserver)
 - Pulmonary Diseases (Chronic Obstructive Pulmonary Disease) = 1.5% (Testretest reliability)
- SMC = 0.5 m/s
- Substantial meaningful change = 0.10 m/s

Global Rating of Change (GRoC)

(‡See Note below)

- MCIC
 - o 2 points on 11-point scale
- MDC
 - o 0.45 points on 11-point scale
- MIC
 - Low Back Pain = 2.5 points on 11-point scale (46)

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

Further work is needed to determine the true value of the GRoC as an outcome measure and in turn as an anchor measure. Several key points have been identified (47):

- 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

Goal Attainment Scale (GAS) (48)

- MDC
 - Cerebral Palsy (Pediatric) = 2.040 (Low Response Group)
 - Cerebral Palsy (Pediatric) = 1.275 (High Response Group)
- SEM
 - Cerebral Palsy (Pediatric) = 0.736 (Low Response Group)
 - o Cerebral Palsy (Pediatric) = 0.460 (High Response Group)

Gross Motor Function Measure-66 (GMFM-66) (49)

- Clinically meaningful improvement (50)
 - 0 = 1.58
- MCID
 - Cerebral Palsy (51)



- Gross Motor Function Classification System Level I: 1.7 -2.7
- Gross Motor Function Classification System Level II: 1.0-1.5
- Gross Motor Function Classification System Level III: 0.7 1.2
- Gross Motor Function Classification System Level Overall: 0.8 1.3

Headache Disability Inventory (HDI) (52)

Decrease of 29 points (95% CI) or more is considered clinically significant

Keele STarT Back Screening Tool (53,54)

- High-risk categories: > 4 (psychosocial subscale scores)
- Medium-risk categories: > 3 (overall tool score) and < 4 (psychosocial subscale scores)
- Low-risk categories: < 3 (overall tool score)

NOTE: No MDC or MCID established

Knee Injury and Osteoarthritis Outcome Score (KOOS)

- MDC
 - o Athletes (55)
 - Pain = 6.1
 - Symptoms = 8.5
 - Activities of Daily Living = 8.0
 - Sports/Rec = 5.8
 - Quality of Life = 7.2
 - o Joint Pain and Fractures = 8 10-point change may represent minimal perceptible clinical improvement (55)
 - Knee Ligament Injury
 - Anterior Cruciate Ligament Reconstruction in Athletic Populations (KOOS subscales) (56)
 - \square Symptoms = 8.5
 - □ Pain = 6.1
 - □ Activities of Daily Living = 8.0
 - □ Sports/recreation = 5.8
 - □ Quality of Life = 7.2
 - Articular Cartilage Lesion (KOOS subscales) (56)
 - \square Symptoms = 11.8
 - □ Pain = 11.2
 - □ Activities of Daily Living = 11.1
 - □ Sports/recreation = 12.1



		Quality of Life = 8.7		
■ Focal Cartilage Repair (KOOS subscales) (56)				
		Symptoms = 5		
		Pain = 6		
		Activities of Daily Living = 7		
		Sports/recreation = 12		
		Quality of Life = 7		
	■ Os	steoarthritis and No Indication for Joint Replacement (KOOS subscales) (56		
		Symptoms = 15.5		
		Pain = 13.4		
		Activities of Daily Living = 15.4		
		Sports/recreation = 19.6		
		Quality of Life = 21.1		
	■ Me	eniscal Injury (with and without surgery) (KOOS subscales) (56)		
		Symptoms = 19.4		
		Pain = 25.7		
		Activities of Daily Living = 20.2		
		Sports/recreation = 35.0		
		Quality of Life = 26.2		
0		arthritis and Joint Replacement = $8 - 10$ -point change may represent al perceptible clinical improvement $^{(55)}$		
0	Young	unger individuals (KOOS subscales) = 14.3 – 19.6 points (57)		
0	Older	Older individuals (KOOS subscales) = ≥ 20 points (57)		
M	CID			
0	Knee			
	■ Art	throplasty (total knee, post)		
		Function = 15.		
		Pain = 13.5 2		
		Quality of Life = 8.0		
	■ Au	tologous Chondrocyte Implantation (KOOS subscale) (56)		
		Symptoms = could not be calculated		
		Pain = 11 - 18.8		
		Activities of Daily Living = 2 - 17.3		
		Sports/recreation = $5 - 18.6$		
		Quality of Life = $8 - 19.6$		
	■ Me	eniscal repair (Post arthroscopic) (58)		



 \square Symptoms = 12.3 □ Pain = 11.8 □ Activities of Daily Living = 11.4 □ Sports/recreation = 16.7 □ Quality of Life = 16.9 Osteochondral Allograft Transplantation (KOOS subscales) (56) Symptoms = could not be calculated □ Pain = 7 □ Activities of Daily Living = could not be calculated □ Sports/recreation = 25 □ Quality of Life = could not be calculated Platelet-rich plasma Injection Treatment (59) □ 6 months after (KOOS subscales) ◆ Symptoms = 8.4 ◆ Pain = 9.3 Activities of Daily Living = 9 ◆ Sports/recreation = 12.5 ◆ Quality of Life = 10.3 □ 12 months after (KOOS subscales) ◆ Symptoms = 8.2 ◆ Pain = 9.1 Activities of Daily Living = 9.2 Sports/recreation = 11.6 ◆ Quality of Life = 10.3 SEM (56) Athletes (mean age 25.6 ± 3.4 years) ■ Pain = 2.2 ■ Symptoms = 3.1 ■ Activities of Daily Living = 2.9 ■ Sports/Rec = 2.1 ■ Quality of Life = 2.6 Knee Ligament Injury Anterior Cruciate Ligament Reconstruction in Athlete (KOOS subscales) \Box Symptoms = 3.1 \Box Pain = 2.2 □ Activities of Daily Living = 2.9



		Sports/recreation = 2.1
		Quality of Life = 2.6
-		terior Cruciate Ligament Tear Within 1 Year or Anterior Cruciate Ligament pair Within 1 Year (KOOS subscales)
		Symptoms = 9.1
		Pain = 6.6
		Activities of Daily Living = 7.8
		Sports/recreation = 12.7
		Quality of Life = 7.6
•	Art	cicular Cartilage Lesion: Autograft Implantation System (KOOS subscales)
		Symptoms = 11.1
		Pain = 9.50
		Activities of Daily Living = 10.7
		Sports/recreation = 10.8
		Quality of Life = 7.4
-	Me	eniscal Injury (with/without Meniscal Surgery) (KOOS subscales)
		Symptoms = 7.0
		Pain = 9.3
		Activities of Daily Living = 7.3
		Sports/recreation = 12.6
		Quality of Life = 9.5
Kn	ee (Osteoarthritis (KOOS subscales)
•	Mil	d Osteoarthritis with Anterior Cruciate Ligament Reconstruction
		Symptoms = 9.0
		Pain = 7.2
		Activities of Daily Living = 5.2
		Sports/recreation = 9.0
		Quality of Life = 7.4
-		oderate Osteoarthritis with High Tibial Osteotomy and Valgus Correction OOS subscales)
		Symptoms = 8.0
		Pain = 9.0
		Activities of Daily Living = 5.8
		Sports/recreation = 11.6
		Quality of Life = 7.4
_	Os	tegarthritis with TKA Revision (KOOS subscales)

0



- \Box Symptoms = 7.2
- □ Pain = 10.1
- □ Activities of Daily Living = 11.7
- □ Sports/recreation = 24.6
- □ Quality of Life = 10.8

Knee Injury and Osteoarthritis Outcome Score for Children (KOOS-Child)

- SEM
 - o Children with Knee Disorders (60)
 - Pain = 5.69
 - Symptoms = 8.14
 - Activities of Daily Living = 5.28
 - Sports/play = 8.02
 - Quality of Life = 7.59
 - o Children with Stable Knee Conditions (61)
 - Pain = 9.9
 - Symptoms = 10.2
 - Activities of Daily Living = 8.9
 - Sports/play = 16.9
 - Quality of Life = 10.5
- MDC
 - o Children with Knee Disorders (60)
 - Pain = 15.78
 - Symptoms = 22.56
 - Activities of Daily Living = 14.64
 - Sports/play = 22.22
 - Quality of Life = 21.03
 - Children with Stable Knee Conditions (61)
 - Pain = 27.3
 - Symptoms = 28.4
 - Activities of Daily Living = 24.7
 - Sports/play = 46.9
 - Quality of Life subscale = 29.2

Knee Outcome Survey (KOS)

MCID (7)

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- Activities of Daily Living = 7.1 percentage points change
- MDC (62)
 - 0 = 11.4

Lower Extremity Functional Scale (LEFS)

- MCID
 - o Ankle Sprains = 4 points (63)
 - Joint Pain and Fractures (64)
 - Anterior Cruciate Ligament reconstruction = 9 points
 - Arthroplasty
 - □ Total knee = 9 points
 - □ Total hip = 9 points
 - Hip Impairment = 6 points or 11.3%
 - Lower Extremity Injury = 9 points
 - o Knee (65)
 - Osteoarthritis = 6.3 points (0-2 months)
 - Osteoarthritis = 7.5 points (0-6 months)
 - Osteoarthritis = 12.5 points (0-12 months)
 - Lower extremity musculoskeletal dysfunction = 9 points (65)
- MDC
 - o Ankle Sprains = 4 points (63)
 - Joint Pain and Fractures (64)
 - Anterior Cruciate Ligament reconstruction = 8.7 points
 - Arthroplasty
 - □ Total knee = 9 points
 - □ Total hip = 9 points
 - Hip Impairment = 7 points or 11.3%
 - Lower Extremity Injury = 9 points
 - o Knee (65)
 - Anterior knee pain = 8 points
 - Osteoarthritis = 19.2 points (at 2 months)
 - Osteoarthritis = 17.6 points (at 6 months)
 - Osteoarthritis = 22.6 points (at 12 months)
 - Total knee arthroplasty = 9 points
 - Lower extremity musculoskeletal dysfunction = 9 points (65)
 - Osteoarthritis



- Hip = 9.9 10 points (65,66)
- Lower extremity = 9 points
- SEM
 - Ankle Sprains = 4 points (63)
 - o Chronic Pain (Orthopaedic Rehab) = 4 points
 - o Joint Pain and Fractures (64)
 - Anterior Cruciate Ligament reconstruction = 3.7 points
 - Arthroplasty
 - □ Total knee = 3.7 points
 - □ Total hip = 3.7 points
 - Lower Extremity Injury = 3.9 points
 - Orthopaedic Rehab = 4 points
 - o Knee (65)
 - Anterior knee pain = 0.10 points
 - Osteoarthritis = 3.4 points
 - Osteoarthritis = 6.9 points (at 2 months)
 - Osteoarthritis = 6.4 points (at 6 months)
 - Osteoarthritis = 8.2 points (at 12 months)
 - Total knee arthroplasty = 3.7 points
 - o Osteoarthritis
 - Hip = 3.6 5.3 points ⁽⁶⁶⁾
 - Orthopaedic Rehab = 4 points
- **NOTE**: 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 (62)

- MDC
 - Knee Injuries (Anterior Cruciate Ligament, meniscal, chondral, patellar dislocation) = 8.9 – 10.1
- SEM
 - Knee Injuries (Anterior Cruciate Ligament, meniscal, chondral, patellar dislocation) = 3.2 − 3.6

Neck Disability Index (NDI)

- MCID
 - Cervical radiculopathy = 7.0 8.5 points $^{(67,68)}$
 - Cervical spine fusion = 7.5 points (67)



- o Mechanical neck disorders = 5 7.5 points (67)
- o Mechanical neck disorders = 19% (67)
- o Mechanical neck pain = 7.5 points (68)
- Neck Pain (non-specific) = 3.5 points (67)

MDC

- $\circ = 10 20\%$
- Cervical radiculopathy = 10.2 13.4 points (67)
- Mechanical neck disorders = 10.2 points (67)
- Mechanical neck disorders = 19.6% (67)
- Mechanical pain = 10.2 points (68)
- Neck pain = 5 points (90% CI) (69)
- o Neck Pain (non-specific) = 8.4 10.5 (67)

SEM

- o Cervical Radiculopathy = $4.4 5.7^{(67)}$
- o Mechanical Neck Disorder = $4.3 8.4^{(67)}$
- o Neck Pain (non-specific) = 3.0 (67)

NOTE: 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.

NOTE: A score of 0% - 20% represents a minimal disability; usually, no treatment is indicated except for 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 (e.g., 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) (70,71)

- MCID (70)
 - o Emergency Room (acute pain) = 1.3 points (70)
 - Low Back Pain (1 week of physical therapy) = 1.5 points
 - Low Back Pain (4 weeks of physical therapy) = 2.2 points
 - Musculoskeletal Pain (Chronic) = 1 point or 15% change
 - Chronic Pain (other; low back pain, OE, diabetic neuropathy, post-herpetic neuralgia, fibromyalgia) = 1.7 points or reduction of 27.9%
 - o Post-operative
 - Abdominal surgery = 56%
 - Orthopedic surgery = 28.6%
 - Other types of surgery = 15.4%
 - Shoulder Pain = 2.17 points (surgical and nonsurgical subjects after 3-4 week of



rehabilitation)

- o Spinal cord injuries (Chronic) = 1.6 1.80 points or 36% (70,71)
- MDC (70)
 - Low Back Pain = 2 points (95% CI)
- SEM (70)
 - o Low Back Pain = 1.02

Oswestry Disability Index (ODI) (72)

- MCIC
 - Lower back = 10 points or a 20% improvement
- MCID (73)
 - Low back pain (anchor based, ROC) = 7.5% 16.7%
 - Lumbar Spine Surgery (anchor based (HTI)) = 9.5 15.4 points
 - Lumbar Spine Surgery (anchor based (ROC)) = 11.8 17.9 points
 - SI Joint Fusion Surgery (anchor based (HTI)) = 19.5% average change
 - SI Joint Fusion Surgery (ROC) = 12.2% 15.0%
 - Spinal Deformity Surgery = 15.0%
- MDC
 - o Back pain = 5.9 6.4 points (90% CI) (73)
 - o Low back pain (subacute and chronic) = 11.1 15.35 (95% CI) (74)
 - o Lumbar fusion = 11.7% 15.5 % (90-95% CI) (73)
- SEM (73)
 - o Back pain (mean duration 6 years) = 4.2 4.6 points
 - o Low/upper back pain (< 1 year) = 2.6% 2.8%
 - Spinal stenosis = 6.1%

NOTE: 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.

NOTE: 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 (e.g., 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 (75)

- MCIC
 - Low Back Pain (chronic) = decrease of 8.5 9.5 points



Patient Specific Functional Scale (PSFS) (76–78)

- MCID (77)
 - Humeral fracture (proximal) = 2 or more points
 - Knee arthroplasty (total) = 3.83 5.13
 - Osteoarthritis (hand) = 2.2-point change
 - Spinal Stenosis = 1.34 points
 - Upper Extremity Musculoskeletal = 1.2 points
- MDC
 - o Chronic pain = 2 points (77)
 - Knee dysfunction = 1.5 (77)
 - Low Back pain = 1.4 points (77)
 - Lower Limb Amputees = 11.2 (90% CI) (77)
 - Neck Dysfunction and Whiplash = 2 points (77)
 - o Older adults = $2.8^{(77)}$
 - Osteoarthritis (hand) = 1.30 (90% CI) 1.56 (95% CI) (77)
 - Single activity score = 3 points (90% CI)
 - Spinal Stenosis = 2.4 points (77)
- SEM
 - o Chronic pain = $0.41^{(77)}$
 - o Knee dysfunction = $0.62 1.0^{(77)}$
 - Knee arthroplasty (total, 3 months post-surgery) = 1.38 1.85 (77)
 - o Lower Limp Amputees = 4.8 (77)
 - Neck dysfunction or pain = 0.43 (76,77)
 - o Older Adults = 1.0 (77)
 - o Osteoarthritis (hand) = 0.56 (77)
 - Spinal Stenosis = 1.03 (77)

NOTE: 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

Peabody Developmental Motor Scales-2nd Edition (PDMS-2) (79)

- MCID (80,81)
 - Intellectual disabilities (includes preschoolers) = 8.39
- MDC (80,81)
 - o Intellectual disabilities (includes preschoolers) = 7.76
- SEM
 - o Cerebral Palsy (80,81)



- Fine Motor Quotient = 2.5
- Gross Motor Quotient = 1.1
- Total Motor Quotient = 1.6
- o Intellectual Disability = 1.80 (80)

Pediatric Balance Scale (82)

- MDC:
 - o Cerebral Palsy
 - Dynamic = 0.96 points
 - Static = 0.79 points
 - Total = 1.59 points
- MDIC
 - Cerebral Palsy
 - Dynamic 2.92
 - Static 2.92
 - Total 5.83

Pediatric Evaluation of Disability Inventory (PEDI) (83)

- MCID
 - Caregiver Assistance
 - = 11.6 (Lickert Scale with range 8.7-14.9)
 - o Functional Skills
 - = 10.9 (Lickert Scale with range 8.7-14.9)
 - Visual Analog Scale (VAS)
 - = 11.5 (mean)
 - = 11.2 (Caregiver Assistance with range 6.0-15.6)
 - = 11.6 (Functional Skills with range 6.0-15.6)
 - Traumatic Brain Injury, Spinal Cord Injury, Lower Extremity Trauma, Nontraumatic Brain Injury, Developmental Disorders
 - = 11 points (mean; all 6 scales)
 - = 11.3 (mean; for Likert Scale categories)

Roland-Morris Disability Questionnaire (RMDQ) (84,85)

- MCID (84)
 - o Low Back Pain
 - Acute, subacute, or chronic = 3.5 points
 - Detect change = 3 points or 30% of baseline score



- Score > 7 then = 3 points
- Score < 7 then = 30% change in score
- Treatment of 3-6 weeks = 5-point change
- MDC (85)
 - o = 7.6 points or a 30% improvement from baseline
- SEM (84)
 - o Low Back Pain = 1.79
 - Lumbar Disc Surgery (post) = 2.0 scale points (95% CI)

NOTE: 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.

Roll Evaluation of Activities of Life (REAL) (86)

- MDC
 - Children without Disabilities (Ages 2-18)
 - ADL = 15.91
 - IADL = 11.08
- SEM
 - Children without Disabilities (Ages 2-18)
 - Activities of Daily Living
 - \Box Average = 5.74
 - □ Preschool = 1.41
 - \Box Elementary = 3.00
 - □ Preadolescent = 2.45
 - \Box Teenage = 4.00
 - Independence with Activities of Daily Living
 - \Box Average = 4.00
 - □ Preschool = 1.73
 - □ Elementary = 2.00
 - □ Preadolescent = 1.41
 - □ Teenage = 2.65
- Mean Standard Scores
 - Children with Disabilities
 - Attention Deficit Disorders: 85.08
 - Autism Spectrum Disorder: 54.53
 - Cerebral Palsy: -6.17
 - Children with Disabilities: 67.14



■ Developmental Delay: 60.34

■ Down Syndrome: 55.17

■ Learning Disabled: 76.32

Sensory Integration Disorders: 88.86

■ Speech Delay: 99.53

Shoulder Pain and Disability Index (SPADI)

- MCID
 - Musculoskeletal Upper Extremity Problems = 13.2 (87)
 - o Pain Upper Extremity = 8 10 points (87,88)
 - o Rotator Cuff Disease = 15.4 (87)
- MDC (87)
 - o Adhesive Capsulitis = 17
 - o Arthroplasty (shoulder) = 18
 - Musculoskeletal Upper Extremity Problems = 18.1
 - o Shoulder Disorders = 21.5
- MIC
 - Shoulder pain = 20 points (43% of baseline) (89)
- SEM
 - o Arthroplasty (shoulder) = 2 (88)
 - o Non-specific population = 4.75 − 11.65 (87)
- SDC
 - Shoulder pain = 19.7 points (89)

NOTE: 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
 - Arthroplasty (anatomic total shoulder) (aTSA) = 1.6 (90)
 - o Arthroplasty (Ream-and-run) (R&R) = 2.6 (90)
 - Arthroplasty (Reverse total shoulder) (rTSA) = 3.7 (90)
 - o Arthroplasty (shoulder) = $2.4 3.0^{(91)}$
 - o Rotator cuff disease = $8.5 9.7^{(91)}$
- MDC (91)
 - Musculoskeletal (shoulder) = 32.3 (95% CI)
- SEM (91)



Musculoskeletal (shoulder) = 4.75 -11.65

Timed Up and Go (TUG)

- Cut-off score indicating risk of falls (92)
 - o Adults = > 13.5 s
 - o Lower extremity amputees = > 19 s
 - o Older adults (fall clinic) = > 15 s
 - o Older adults (frail) = > 32.6 s
 - o Osteoarthritis (hip) = > 10 s
 - o Parkinson's Disease = > 7.95 11.5 s
 - o Stroke (older adults) = > 14 s
 - o Vestibular disorders = > 11.1 s

MCID

 Lumbar degenerative disc disease (post-surgery) = 2.1 s (or TUG z score change of 1.5) (93)

MDC

- o Alzheimer's disease = 4.09 s (92)
- o Arthroplasty (Total hip) = 1.62 s (95% CI) (94)
- o Parkinson's Disease = $3.5 11 \text{ s}^{(92,95)}$
- o Spinal cord injury = 10.8 s (30% difference) (92,96)
- o Stroke (chronic) = $2.9 s^{(92)}$

SEM

- o Arthroplasty (Total hip) = 0.59 s (94)
- o Alzheimer's disease (92)
 - All = 2.48 s
 - Mild to Moderate = 1.52 s
 - Moderately severe to Severe = 3.03 s
- o Cerebral Palsy (97)
 - Evening trial = 0.4 s
 - Morning trial = 0.6 s
 - Spastic diplegia mean TUG score = 10.1 s
 - Spastic hemiplegia mean TUG score = 8.4 s
 - Spastic quadriplegia mean TUG score = 28 s
 - Trials administered 5 minutes apart = 0.19 s
 - Trials administered 1 week apart = 0.32 s
- o Parkinson's Disease = 1.75 s (92,95)



- o Spinal cord injury = $3.9 \text{ s}^{(92,96)}$
- o Stroke (chronic) = $1.14 \text{ s}^{(92)}$

NOTE: 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

Tinetti Performance Oriented Mobility Assessment (POMA) (98)

- Cut-Off Scores
 - o Older adults = 19
 - o Older adults (frail) = 11
 - o Parkinson's Disease = < 20
 - o Stroke (chronic) = < 20
- MDC
 - o Older adults
 - Individual assessment = 4.0 4.2 points
 - Group assessment = 0.7 0.8 points
 - Stroke = 6 points

Upper Extremity Functional Index/Scale (UEFI/UEFS) (99)

- MCID
 - o UEFI-20 = 8 (95% CI)
 - o UEFI-15 = 6.7 (95% CI)
- MDC₉₀
 - o UEFI-20 = 9.4 (95% CI)
 - o UEFI-15 = 8.8 (95% CI)
 - o UEFS = 9.8 (95% CI)

NOTE: UEFI-20 is a 20-item Upper Extremity Functional Index (0-80, higher scores indicate better function). UEFI-15 is a 15-item Upper Extremity Functional Index (0-100, higher scores indicate better function). UEFS is an Upper Extremity Functional Scale (8-80, lower scores indicate better function.

Visual Analog Scale (VAS) Scores

- MCID
 - Hand surgery (post-operative) = 1.6 1.9 (100)
- MDC
 - Vestibular Disorders (Head Movement) = 4.57 (101)
- Minimum of a 2-point change on a 0-10 pain scale
- SEM



o Vestibular Disorders (Head Movement) = 1.65 (101)

Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC)

- MCID
 - o Arthroplasty (total knee, post) (102)
 - Function = 9
 - Pain = 11
 - Stiffness = 8
 - Total score = 10
 - o Osteoarthritis
 - Hip or knee = 12% change from baseline
 - Hip (total replacement) (103)
 - □ Pain = 29.26
 - □ Stiffness = 25.91
 - Knee (103)
 - \square 2 months = 4 8.8
 - \Box 6 months = 6.6 6.8
 - \Box 12 months = 1.6 12.0
 - Knee (total replacement) (103)
 - □ 6 months = 11.5
 - □ 12 months = 11.5
 - Lower extremity = 17 22% change from baseline
- MDC (103)
 - Knee (total replacement)
 - 6 months = 10.9 (95% CI)
 - 12 months = 15.3 (95% CI)
 - Hip (total replacement)
 - Function = 11.93
 - Pain = 21.38
 - Stiffness = 27.98
 - Osteoarthritis
 - Hip = 9.1 points (95% CI)
 - Hip and Knee pain = 3.94 (90% CI)
 - Knee
 - \Box 2 months = 14.1 (95% CI)



- \Box 6 months = 15.0 (95% CI)
- □ 12 months = 18.5 (95% CI)
- MIC
 - o Arthroplasty (total knee, post) (102)
 - Function = 16
 - Pain = 21
 - Stiffness = 13
 - Total score = 17
- SEM
 - o Hip (total replacement) (103)
 - Pain subscale (6 months post) = 7.71
 - Physical function (6 months post) = 4.30
 - Stiffness subscale (6 months post) = 10.10
 - o Knee (total replacement) (103)
 - 6 months = 3.9
 - 12 months = 5.5
 - Pain subscale (6 months post) = 8.08
 - Physical function (6 months post) = 4.73
 - Stiffness subscale (6 months post) = 10.50
 - o Osteoarthritis (103)
 - Hip = 3.3
 - Knee
 - \square 2 months = 5.1
 - \Box 6 months = 5.4
 - □ 12 months = 6.7
 - Osteoarthritis (Older individuals with hip or knee)
 - Pain = 0.58
 - Physical function = 1.65
 - Stiffness = 0.62



CODING AND STANDARDS

Applicable Lines of Business

×	CHIP (Children's Health Insurance Program)
×	Commercial
×	Exchange/Marketplace
×	Medicaid
⊠	Medicare Advantage

BACKGROUND

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

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 and include sufficient clinical documentation, so that a peer reviewer can render a reasonable determination on baseline functional status and/or treatment response.

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, 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.

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 maximum therapeutic benefit (MTB) is appropriate.

Definitions

Episode of Care

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

Lasting, Sustainable Progress

Progress made by the patient has been maintained at a reasonable level over a reasonable period of time.

Maximum Therapeutic Benefit (MTB)

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

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 Clinically Important Difference (MCID)

MCID is the smallest change in an outcome that a patient would identify as important.

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 Important Change (MIC)

A threshold for a minimal within-person change over time, above which patients perceive themselves as importantly changed

Outcome Measures

- Objective, measurable assessments by the clinician to determine patient progress with treatment
- 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
- Used with other standardized tests and measures throughout the episode of care as part of periodic reexamination to provide information about whether predicted outcomes are being realized
- Refers to the systematic collection (data gathered at multiple time points using same methods) and analysis of information that is used to evaluate the efficacy of an intervention

Patient Acceptable Symptom State (PASS)

PASS is defined as the point at which the patient considers themselves well, recovered, and satisfied with treatment.

Smallest Detectable Change (SDC)

A value for the minimum change that needs to be observed to know that the observed change is real and not potentially a product of measurement error.

Smallest Real Change (SRC)

Meaningful improvement can occur only when there is a potential for MCIC. The timelines for improvement may not be applicable to some types of post-surgical care.

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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.

Standard Error of Measurement (SEM)

Estimates the standard error in a set of repeated scores.

Treatment Goals

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

POLICY HISTORY

Date	Summary
November 2024	This guideline replaces Evolent_CG_605 for Measurable Progressive Improvement
	Removed the CPT Codes section from Coding
	 Updated numerical indications based upon clinical literature, where appropriate
	 Added Knee Injury and Osteoarthritis Outcome Score for Children (KOOS-Child) as a new section in the Indications
	 Editorial changes to match the formatting and layout of the Evolent template
	Removed duplicate/unnecessary references for concision
December 2023	Measurable improvement thresholds added
	Editorial changes
	References updated

LEGAL AND COMPLIANCE

Guideline Approval

Committee

Reviewed / Approved by Evolent Specialty Clinical Guideline Review Committee

Disclaimer

Evolent Clinical Guidelines do not constitute medical advice. Treating health care professionals are solely responsible for diagnosis, treatment, and medical advice. Evolent

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Evolent Clinical Guideline 1504 for Measurable Progressive Improvement



uses Clinical Guidelines in accordance with its contractual obligations to provide utilization management. Coverage for services varies for individual members according to the terms of their health care coverage or government program. Individual members' health care coverage may not utilize some Evolent Clinical Guidelines. A list of procedure codes, services or drugs may not be all inclusive and does not imply that a service or drug is a covered or non-covered service or drug. Evolent reserves the right to review and update this Clinical Guideline in its sole discretion. Notice of any changes shall be provided as required by applicable provider agreements and laws or regulations. Members should contact their Plan customer service representative for specific coverage information.



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