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

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

Purpose
This policy will be used to provide minimal clinical thresholds using specific, measurable, and functional treatment goals and/or outcome measures in the determination of improved, lasting and sustained outcomes. These thresholds will assist in medical necessity reviews of billed clinical services by network practitioners.

Scope
Physical medicine practitioners, including chiropractors, physical therapists, occupational therapists, and speech language pathologists.

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

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

Specific, Measurable, and Functional Goals:
Clearly defined goals of treatment that allow measurement of the amount and/or degree of meaningful change over time. These goals are often determined by the use of functional outcome assessment tools, as defined in Clinical Guideline, Plan of Care

Outcome Measures:
Objective, measurable assessments by the clinician to determine patient progress with treatment. The use of standardized tests and measures at the onset of care establishes the baseline status of the patient, providing a means to quantify change in the patient’s functioning. Outcome measures, along with other standardized tests and measures used throughout the episode of care, as part of periodic reexamination, provide information about whether predicted outcomes are being realized. Outcomes measurement refers to “…the systematic collection and analysis of information that is used to evaluate the efficacy of an intervention” (Clark & Gironda, 2002). Systematic collection means that data are gathered at multiple time points using the same methods or instruments. Analysis refers to the process of condensing and examining the data to identify meaningful trends or changes. The World Health Organization defines an outcome measure as a “change in the health of an individual, group of people, or population that is attributable to an intervention or series of interventions.”

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

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

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

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

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

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

It is the responsibility of the treating practitioner to maintain a patient record that includes periodic measures of treatment response by employing valid, reliable and relevant outcome assessment tools. Further, it is the responsibility of the treating practitioner to include
sufficient clinical documentation, so that a peer reviewer can render a reasonable determination on baseline functional status and/or treatment response. Further meaningful improvement can occur only when there is a potential for MCIC. When progress towards goals is such that outcome measures approximate normative data for asymptomatic populations or are indicative of mild deficits, which can typically be managed through home exercise or other self-care, then a determination of MTB is appropriate.

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

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

In order to make a valid and reliable determination of meaningful progress toward goals (MCIC) and/or Maximum Therapeutic Benefit-MTB, it is essential that the record include a relevant standardized outcome assessment tool. Progress towards goals should be assessed at predetermined time periods, supported by anticipated meaningful clinical change based on treatment plan goals. Typically, recovery patterns for neuromusculoskeletal conditions involving the low back, neck, and headache disorders show that >50% of the overall improvement with care occurs within 4-6 weeks. When patients are categorized via predictive modeling, the percentage of those showing significant improvement within 6 weeks rises considerably. Studies have consistently shown that short term treatment response is predictive of long term outcomes. McGorry showed that exacerbations of LBP resolved within a few days (52%); within a week (16%); within two-three weeks (26%); even severe flare-ups usually resolved within nine days. After a review of the scientific evidence Magellan Healthcare has concluded all practitioner records must evaluate and document whether treatment is resulting in progressive and sustained improvement.

The practitioner records must demonstrate clear, specific and measurable improvement in the patient’s pain and function every two weeks, or at regular intervals as appropriate for the documented condition, as measured by one or more of the following examples of methods for each anatomic region. If no functional tool is available for the patient’s condition it is expected the practitioner will develop specific, measurable, and functional goals:

- **6-Minute Walk test (6MWT) for Older Adults**
  - MDC (calculated from standard error of measurement (SEM)) = 58.21 m (190.98 ft) (Perera et al, 2006)
  - SEM Older people with limited mobility: 21 m (Perera et al, 2006)
  - Older people with stroke: 22 m (Perera et al, 2006)
- **Activities of Daily Living Scale of the Knee Outcome Survey**
  - 10-30% reduction in the global score
- **Berg Balance Scale**
• MDC=4.7 points
  • MDC=6.5 points
- Bournemouth – Back Questionnaire
  • A change of 17 points or 47% is considered clinically significant improvement.
- Bournemouth – Neck Questionnaire
  • A change of 13 points or 34% is considered clinically significant improvement.
- Dizziness Handicap Inventory
  • MDC = 17.18 points
- Dynamic Gait Index
  • MDC=2.9 points
  • Score of 19 or less found to be predictive of falls
- Functional Gait Assessment
  • MCID=4 points
- Functional Rating Index
  • A 10% absolute change represents minimal clinically important change
  • MCIC = 8.4%
- FOTO or Functional Status (FS) measure:
  • The MCII (Minimally Clinically Important Improvement) and MDC (Minimal Detectable Change) are stated on the assessment report. For significant, minimal improvement, the patient status should increase by the MDC value. FOTO summary report is available upon request.
- Gait Speed for Older Adults
  • Small meaningful change=.5m/sec (Perera et al, 2006)
  • Substantial meaningful change=.10m/sec (Perera et al, 2006)
  • Meaningful change for those with stroke undergoing rehab=.175 m/sec
- Headache Disability Inventory (HDI)
  • Authors of the index have determined that a decrease of 29 points or more is considered clinical significant
- LEFS
  • 10% improvement on the global score
- Neck Disability Index
  • The minimal detectable change is 10% (approximately 5 points). Clinically meaningful change is considered to be 30-50% (approximately 15 points).
- Oswestry Disability Index
  • The minimal detectable change is 10.5 points. Clinically meaningful change is considered to be 30-50%.
- Pain Disability Index
  • A decrease of 8.5-9.5 points is considered clinically important
- Patient Specific Functional Scale
  • Minimum detectable change (90%CI) for average score = 2 points
  • Minimum detectable change (90%CI) for single activity score = 3 points
- Roland-Morris Disability Questionnaire
  • Minimal Important Change=5pts
  • A 30% change in RMQ score is considered meaningful with 50% considered substantial.
- Keele STarT Back Screening Tool
  • No MDC or MCID established.
- Low, Medium and High risk categories established for subscales and overall score
- Shoulder Pain and Disability Index
  - 10-30% reduction on the global score
- Timed Up and Go (TUG)
  - Cut-off score of 13.5 sec or longer is predictive of falls
- Tinetti (POMA)
  - MDC= 5 Points
- VAS scores
  - Minimum of a 2 point change on a 0-10 pain scale

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

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

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

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


Evans R, et al. A Pilot Study for a Randomized Clinical Trial Assessing Chiropractic Care, Medical Care and Self-Care Education for Acute and Subacute Neck Pain Patients. JMPT 2003; 26(7):403-411


Kvien TK, Heiberg T, Hagen KB. Minimally clinically important improvement/difference (MCII/MCID) and patient acceptable symptom state (PASS): What do these concepts mean? Ann Rheum Dis 2007;66:iii40-iii41.


