

National Imaging Associates, Inc.	
Clinical guidelines MEASURABLE PROGRESSIVE IMPROVEMENT	Original Date: November 2, 2015
Physical Medicine – Clinical Decision Making	Last Revised Date: December 2019 <u>October 2021</u>
Guideline Number: NIA_CG_605	Implementation Date: <u>July 2021</u>

Policy Statement

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

Purpose

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

Acceptable Thresholds of Measurable Improvement:

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

~~In order to~~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 and supported by anticipated meaningful clinical change based on treatment plan goals. Typically, recovery patterns for neuromusculoskeletal conditions involving the low back, neck, and headache disorders show that > 50% of the overall improvement with care occurs within 4 - 6 weeks. When patients are categorized via predictive modeling, the percentage of those showing significant improvement within 6 weeks rises considerably.¹⁻⁴ Studies have consistently shown that short-term treatment response is

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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 (McGorry, 2000).⁵ After a review of the scientific evidence, this organization has concluded all practitioner records must evaluate and document whether treatment is resulting in progressive and sustained improvement.

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

- 6-Minute Walk test (6MWT) for Older Adults^{6, 7}
 - ~~MDC⁸ (calculated from standard error of measurement (SEM)) = 58.21 m (190.98 ft) (Perera, 2006)~~
 - SEM SMC - Older people with limited mobility⁸: 21 m ~~(Perera, 2006)~~ (69 feet)
 - SMC - Older people with stroke⁸: 22 m ~~(Perera, 2006)~~ (72 feet)
 - MDC - Alzheimer's Disease^{8, 9}: 33. ~~47.5~~ m ~~(Ries, 2009)~~ (110 feet)
 - Either hip OA or knee OA that later received a total joint replacement¹⁰: 61.24m
- Activities of Daily Living Scale of the Knee Outcome Survey
 - 10 - 30% reduction in the global score
 - MCID = 7.1%¹¹ ~~(Piva, 2009)~~
- Activity-Specific Balance Confidence Scale (ABC)
 - ~~_____SMC – older adults¹² = 7 points~~
 - MDC - Parkinson's Disease^{13, 14} = 11 – 13%~~11~~ points
 - ○ MDC – CVA^{15, 16} = 14%
- Berg Balance Scale
 - MDC = 6.2 - 6.5 points^{17, 18} ~~(Romero, 2011)~~
 - MDC – older adults¹⁹ = 10.5 points
 - MDC - Parkinson's Disease¹⁴ = 5 points
 - MDC – chronic stroke²⁰ = 2.7 points
- Bournemouth – Back Questionnaire
 - A change of 26 points in acute conditions and 18 points in subacute/chronic conditions ~~(Newell, 2010)~~.²¹ It is recommended that the Bournemouth be used at baseline and for every 2 - 4 weeks or 6 - 12 visits thereafter within the treatment program to measure progress.
- Bournemouth – Neck Questionnaire
 - A change of 13 points or 36% is considered clinically significant improvement (Bolton, 2004).²² 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)²³
 - Minimal Detectable Change (MDC):
 - Children aged 3-6 years with intellectual disability
 - MDC=7.4 (BOT-2-SF Standard Scores)
 - Children aged 4-21 years who demonstrated an IQ of less than 70, no emotional disturbance, and participated in physical or occupational therapy: N=100 with intellectual disability
 - MDC=4.2 (aged 4-12 years) / 7.4 (aged 13-21 years) (standard scores)
- Disability of Arm, Shoulder, and Hand (DASH, qDASH)²⁴⁻²⁶
 - DASH MCID = 11-15 points
 - QuickDASH MCID = 116.8-15 points
- Dizziness Handicap Inventory
 - MDC = 17.18 points²⁷ ~~(Yorke, 2013)~~
- Dynamic Gait Index
 - MDC = 2.9 points¹⁷ ~~(Romero, 2011)~~
- Falls Self Efficacy Scale/Falls Efficacy Scale-International (FES-I)²⁸⁻³⁰
 - MDC - vestibular disorders²⁸ = 8.2 points
 - ²⁹MDC - hip fracture³⁰ = 17.7 points
- Foot and Ankle Ability Measures (FAAM)^{31, 32}
 - ADL subscale MCID = 8 points
 - Sport subscale MCID = 9 points
- Fear Avoidance Belief Questionnaire (FAB-Q)³³
 - —MCIC – following arthroscopic subacromial decompression³⁴ = -5.0
 - —MDC – low back pain = -5.4
- Functional Gait Assessment
 - MCID = 4 points
- Functional Rating Index
 - A 10% absolute change represents minimal clinically important change³⁵ ~~(Feise, 2010)~~
 - MCID = 8.4%
 - It is recommended that for acute and subacute conditions the FRI be used at baseline and every 1 week or 3 visits thereafter. It is recommended that for chronic conditions the FRI be used at baseline and every 2 weeks or 6 visits thereafter. If the score does not improve by at least 10% (absolute change) in any two successive two-week periods, you should pursue a change in management.
- FOTO or Functional Status (FS) measure^{36, 37}:
 - 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 change⁸ = .5m/sec (~~Perera, 2006~~)
 - Substantial meaningful change⁸ = .10m/sec (~~Perera, 2006~~)
 - Meaningful change for those with stroke undergoing rehab = .175 m/sec
 - MDC – heart failure³⁸ = 0.05 m/s
 - MCID – heart failure³⁸ = 0.05 – 0.12 m/s
 - MDC – joint pain and fractures³⁹ = 0.08 m/s
 - MCID – joint pain and fractures³⁹ = 0.1 m/s
- Global Rating of Change (GROC)⁴⁰⁻⁴² (*See Note below)
 - MDC 0.45 points on 11-point scale
 - MCIC 2 points on 11-point scale
- Gross Motor Function Measure-66 (GMFM-66)⁴³
 - Clinically meaningful improvement = 1.58
- Headache Disability Inventory (HDI)
 - Authors of the index have determined that a decrease of 29 points or more is considered clinically significant (~~Jacobson, 1994~~).⁴⁴
- Keele STarT Back Screening Tool
 - No MDC or MCID established.
 - Low, Medium and ~~High~~ High-risk categories established for subscales and overall score
- Knee Injury and Osteoarthritis Outcome Score (KOOS)^{45, 46}
 - ~~Extension of the WOMAC assessment~~
 - ~~Pain subscale MDC = 22 points~~
 - ~~Stiffness subscale MDC = 29 points~~
 - ~~Physical Functional subscale MDC = 13 points~~
 - ~~Other subscale MDC: 14 points~~ MDCs of KOOS subscales for younger individuals = 14.3 – 19.6 points
 - MDCs of KOOS subscales for older individuals = ≥20 points
- Knee Outcome Survey
 - MDC = 9 points
 - MCID = 7 points
- Lower Extremity Functional Scale (LEFS)
 - MDC = 9 points.
 - MCID = 8 – 9.49 points (~~Brinkley, 1999~~).^{47, 48} It is recommended that the LEFS be used at baseline and for every 2 - 4 weeks or 6 - 12 visits thereafter within the treatment program to measure progress.
- Lysholm Knee Rating System
 - MDC = 10 points
- Neck Disability Index
 - MDC = 10 ~~– 20% points~~^{49, 50} (~~Young, 2009~~) ~~or 20%~~. It is recommended that the Neck Disability Index be used at baseline and for every 2 weeks thereafter within the treatment program to measure progress. A score of 0% - 20% represents a

minimal disability. Usually no treatment is indicated, apart from advice on posture, physical fitness, and diet. Patients often do not score the Neck Disability items as zero, once they are in treatment. The practitioner should consider the patient's prior level of function when goal writing (for example, if the patient's prior level of function would place them in the minimal disability category, their goal should not be to obtain a zero score).

- Numeric Pain Rating Scale
 - MCID = 2 points⁵¹ ~~(Childs, 2005)~~
- Oswestry Disability Index
 - The Minimal Important Change is 10 points or a 20% improvement ~~(Smeets, 2011)~~.⁵² It is recommended that the Oswestry Disability Index be used at baseline and for every 2 weeks thereafter within the treatment program to measure progress. A score of 0% -20% represents a minimal disability. Usually no treatment is indicated, apart from advice on lifting, sitting posture, physical fitness, and diet. Patients often do not score the Oswestry items as zero once they are in treatment. The practitioner should consider the patient's prior level of function when goal writing (for example, if the patient's prior level of function would place them in the minimal disability category, their goal should not be to obtain a zero score).
- Pain Disability Index
 - A decrease of 8.5 - 9.5 points is considered clinically important
- Patient Specific Functional Scale (PSFS)⁵³⁻⁵⁶
 - MDC (90% CI) for average score = 2 points
 - MDC (90% CI) for single activity score = 3 points ~~(Stratford, 1995)~~.⁵⁶ It is recommended that the PSFS be used at baseline and for every 2 - 4 weeks or 6 - 12 visits thereafter within the treatment program to measure progress.
 - MCID in individuals with knee dysfunction, cervical radiculopathy, or chronic low back pain = 2.0 – 3.0 points^{54, 55}
- Peabody Developmental Motor Scales-2nd Edition (PDMS-2)⁵⁷
 - Minimal Detectable Change (MDC) MDC for preschoolers with intellectual disabilities⁵⁸ = 7.76
 - MCID for preschoolers with intellectual disabilities⁵⁸ = 8.39
~~— 7.76; “SATISFACTORY” FOR USE WITH PRESCHOOLERS WHO HAVE INTELLECTUAL DISABILITY (WUANG ET AL, 2012)~~
~~— MINIMAL CLINICALLY IMPORTANT DIFFERENCE (MCID)~~
~~— 8.39 (WUANG ET AL, 2012)~~
- Pediatric Balance Scale⁵⁹
 - MDC:
 - CP total 1.59
 - Static 0.79
 - Dynamic 0.96
 - MDIC:
 - CP total 5.83

▪ Static 2.92

⊖▪ Dynamic 2.92

- Roland-Morris Disability Questionnaire
 - MDC = 7.6 points⁶⁰ ~~(Froud, 2010)~~ or a 30% improvement from baseline ~~(Smeets, 2011)~~.⁵² It is recommended that the RMDQ be used at baseline and for every 2 - 4 weeks or 6 - 12 visits thereafter within the treatment program to measure progress.
- Shoulder Pain and Disability Index
 - The smallest detectable change is 19.7 points, and the minimal important change is 20 points ~~(Thoomes de Graff, 2017)~~.⁶¹ 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.
- Timed Up and Go (TUG)⁶²
 - Cut-off score of 13.5 sec or longer is predictive of falls; however, the Timed Up and Go test has limited ability to predict falls in community dwelling elderly and should not be used in isolation to identify individuals at high risk of falls in this setting ~~(Barry, 2014)~~.⁶³
 - MDC – Alzheimer disease⁶² = 4.09 sec
 - MDC – chronic stroke^{62, 64} = 2.9 sec
 - MDC – Parkinson’s disease^{14, 62, 65, 66} = 3.5 – 11 sec
- Tinetti (POMA)
 - MDC= 5 Points⁶⁷ ~~(Faber, 2006)~~
- VAS scores
 - Minimum of a 2 point change on a 0 - 10 pain scale
- Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC)⁶⁸
 - After TKA- MCID=10, MIC (minimal important change) = 17
 - MCID for LE OA= changes of 17-22% of baseline scores

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

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

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

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

BACKGROUND

Definitions

Treatment Goals

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

Episode of Care

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

Specific, Measurable, and Functional Goals

Clearly defined goals of treatment that allow measurement of the amount and/or degree of meaningful change over time. These goals are often determined by the use of functional outcome assessment tools, as defined in Clinical Guideline, ~~Plan of Care~~ Record Keeping and Documentation Standards.

Outcome Measures

Objective, measurable assessments by the clinician to determine patient progress with treatment. The use of standardized tests and measures at the onset of care establishes the baseline status of the patient, providing a means to quantify change in the patient's functioning. Outcome measures, along with other standardized tests and measures used throughout the episode of care, as part of periodic reexamination, provide information about whether predicted outcomes are being realized. Outcomes measurement refers to the systematic collection and analysis of information that is used to evaluate the efficacy of an intervention. Systematic collection means that data are gathered at multiple time points using the same methods or instruments. Analysis refers to the process of condensing and examining the data to identify meaningful trends or changes. The World Health Organization defines an outcome measure as a "change in the health status of an individual, group ~~of people~~, or population ~~that~~ which is attributable to a planned intervention or series of interventions...."⁶⁹

Lasting, Sustainable Progress

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

Minimally Clinically Important Change (MCIC)

The smallest change in the outcome assessment score that the patient perceives as beneficial, i.e., clinically meaningful improvement.

Minimal Detectable Change (MDC)

The minimal detectable change is the smallest change in score than can be detected beyond random error and is dependent upon sample distribution.

Minimal Clinically Important Difference (MCID)

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

Maximum Therapeutic Benefit (MTB)

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

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

It is the responsibility of the treating practitioner to maintain a patient record that includes periodic measures of treatment response by employing valid, reliable, and relevant outcome assessment tools. Further, it is the responsibility of the treating practitioner to include sufficient clinical documentation, so that a peer reviewer can render a reasonable determination on baseline functional status and/or treatment response. Also, meaningful improvement can occur only when there is a potential for MCIC. When progress towards goals is such that outcome measures approximate normative data for asymptomatic populations or are indicative of mild deficits, which can typically be managed through home exercise or other self-care, then a determination of MTB is appropriate. Most individuals can expect to notice measurable improvement in pain and/or disability within 2 to 6 weeks after beginning treatment. If improvement has not occurred with 6 weeks of treatment, it is highly unlikely that continuing treatment will be helpful. When initial improvement did occur, many studies showed no additional lasting improvement beyond 6 to 12 weeks of treatment. Most flare-ups resolve quickly – within a few days to 3 weeks. The timelines for improvement may not be applicable to some types of post-surgical care (Axen, 2005; Leboeuf, 2005; Kohlbeck, 2005; Hurwitz, 2006; Newell, 2007; Bove, 1998; Moraska, 2007; Borman, 2008; Thiel, 2008).⁷⁰⁻⁷⁸

Patient Acceptable Symptom State (PASS)

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

POLICY HISTORY SUMMARIES:

<u>Date</u>	<u>Summary</u>
<u>December 2021</u>	<ul style="list-style-type: none"> • <u>Added “General Information” statement</u> • <u>Under 6MWT</u> <ul style="list-style-type: none"> ○ <u>Removed MDC calculated from SEM of 58.21 m (190.98 ft)</u> ○ <u>For older people with limited mobility, changed “SEM” to “SMC”</u> ○ <u>Added either hip OA or knee OA that later received a total joint replacement</u> • <u>Updated MDCs for Activity-Specific Balance Confidence Scale (ABC)</u> • <u>Added Bruininks-Oseretsky Test of Motor Proficiency, 2nd Edition (BOT-2)</u> • <u>Updated QuickDASH MCID</u> • <u>Updated Falls Self Efficacy Scale/Falls Efficacy Scale-International (FES-I) MDC values</u> • <u>Added following arthroscopic subacromial decompression MCIC to FAB-Q</u> • <u>Added heart failure, joint pain, and fracture (MDC and MCID) to Gait Speed for Older Adults</u> • <u>Added Gross Motor Function Measure-66 (GMFM-66)</u> • <u>Simplified MDCs for KOOS</u> • <u>Updated MCID for LEFS</u> • <u>Updated MDC of Neck Disability Index</u> • <u>Added Peabody Developmental Motor Scales-2nd Edition (PDMS-2)</u> • <u>Added Pediatric Balance Scale</u> • <u>Added MCID in individuals with knee dysfunction, cervical radiculopathy, or chronic low back pain to PSFS</u> • <u>Added Alzheimer disease, Parkinson disease, and chronic stroke MCDs to TUG</u>
<u>October 2020</u>	<u>Added MCID numbers for WOMAC</u>
<u>January 2020</u>	<ul style="list-style-type: none"> • <u>Under the sub-head Acceptable Thresholds of Measurable Improvement Activity-Specific Balance Confidence Scale was added:</u> <ul style="list-style-type: none"> ○ <u>Activities of Daily Living Scale of the Knee Outcome Survey</u> <ul style="list-style-type: none"> ▪ <u>Activity-Specific Balance Confidence Scale (ABC)</u> ○ <u>Disability of Arm, Shoulder, and Hand (DASH, gDASH)</u>

	<ul style="list-style-type: none"> ▪ <u>DASH MCID = 11-15 points</u> ▪ <u>QuickDASH MCID = 11-15 points</u> ○ <u>Falls Self Efficacy Scale</u> ○ <u>MDC = 8.2 points</u> • <u>Foot and Ankle Ability Measures (FAAM)</u> <ul style="list-style-type: none"> ○ <u>ADL subscale MCID = 8 points</u> ○ <u>Sport subscale MCID = 9 points</u> • <u>Fear Avoidance Belief Questionnaire (FAB-Q)</u> • <u>Global Rating of Change (GRoOC)</u> <ul style="list-style-type: none"> ○ <u>MDC .45 points on 11 point scale</u> ○ <u>MCIC 2 points on 11 point scale</u> • <u>Knee Injury and Osteoarthritis Outcome Score (KOOS)</u> <ul style="list-style-type: none"> ○ <u>Extension of the WOMAC assessment</u> ○ <u>Pain subscale MDC = 22 points</u> ○ <u>Stiffness subscale MDC = 29 points</u> ○ <u>Physical Functional subscale MDC = 13 points</u> ○ <u>Other subscale MDC: 14 points</u> • <u>Knee Outcome Survey</u> <ul style="list-style-type: none"> ○ <u>MDC = 9 points</u> ○ <u>MCID = 7 points</u> • <u>Lysholm Knee Rating System</u> <ul style="list-style-type: none"> ○ <u>MDC = 10 points</u> • <u>Oswestry Disability Index: The Minimal Important Change is 10 points or a 20% improvement (Previously 30% improvement)</u>
<u>July 2019</u>	<ul style="list-style-type: none"> • <u>Definitions moved to the background</u> • <u>Minor grammar and format edits</u> • <u>Check validity of references with one addition – some references are from older sources however the information is still relevant</u>

July 30, 2019

- ~~Definitions moved to the background~~
- ~~Minor grammar and format edits~~
- ~~Check validity of references with one addition – some references are from older sources however the information is still relevant~~

January 2020

- ~~Under the sub-head Acceptable Thresholds of Measurable Improvement Activity-Specific Balance Confidence Scale was added:~~
 - ~~Activities of Daily Living Scale of the Knee Outcome Survey~~
 - ~~Activity Specific Balance Confidence Scale (ABC)~~
 - ~~Disability of Arm, Shoulder, and Hand (DASH, qDASH)~~
 - ~~DASH MCID = 11-15 points~~
 - ~~QuickDASH MCID = 11-15 points~~
 - ~~Falls Self Efficacy Scale~~
 - ~~MDC = 8.2 points~~
- ~~Foot and Ankle Ability Measures (FAAM)~~
 - ~~ADL subscale MCID = 8 points~~
 - ~~Sport subscale MCID = 9 points~~
- ~~Fear Avoidance Belief Questionnaire (FAB-Q)~~
- ~~Global Rating of Change (GROC)~~
 - ~~MDC .45 points on 11 point scale~~
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- ~~Lysholm Knee Rating System~~
 - ~~MDC = 10 points~~
- ~~Oswestry Disability Index: The Minimal Important Change is 10 points or a 20% improvement (Previously 30% improvement)~~

October 2020

- ~~Added MCID numbers for WOMAC~~

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Physical Medicine



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Reviewed/Approved by NIA Clinical Guideline Committee

GENERAL INFORMATION

It is an expectation that all patients receive care/services from a licensed clinician. All appropriate supporting documentation, including recent pertinent office visit notes, laboratory data, and results of any special testing must be provided. If applicable: All prior relevant imaging results and the reason that alternative imaging cannot be performed must be included in the documentation submitted.

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