

Determination of Maximum Therapeutic Benefit

Optum Health Solutions Musculoskeletal (MSK)
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Policy Statement

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 supervised 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 health record to reliably validate the response to treatment.

It is the responsibility of the treating health care provider to maintain a patient health care 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 health care provider to include sufficient data in clinical submissions, so that a peer reviewer can render a reasonable determination on baseline status and/or treatment response. See Appendix A for the MTB decision-making flow chart.

Once MTB has been determined, the treating health care provider is accountable to one of the following:

- Amend the current plan of care based upon current best-evidence
- Refer the patient for an appropriate therapeutic regimen
- Discharge the patient from the current therapeutic regimen

Purpose

This policy provides the clinical criteria for the determination of MTB in the management of neuromusculoskeletal disorders. Additionally, the policy acknowledges individual health care provider accountabilities in assessing for MTB and appropriate clinical decision-making once MTB has been reached.

Scope

This policy applies to all in and out of network programs involving all provider types, where utilization review determinations about MTB are rendered. The guideline also serves as a resource for peer-to-peer interactions in describing the position of Optum on the determination of maximum therapeutic benefit.

Certain internal policies may not be applicable to self-funded members and certain insured products. Refer to the member's Summary Plan Description (SPD) or Certificate of Coverage (COC) to determine whether coverage is provided or if there are any exclusions or benefit limitations applicable to any of these policies. If there is a difference between any policy and the member's SPD or COC, the member's SPD or COC will govern.

Definitions

Maximum Therapeutic Benefit (MTB): The application of the current therapeutic regimen has achieved its full potential benefit for this episode of the condition for which it was applied.

Minimum Clinically Important Difference (MCID): The smallest change in the outcome assessment score (OA) that the patient perceives as beneficial i.e., clinically meaningful improvement.

Episode of pain: A period of pain lasting > 24 hours, preceded and followed by a period of at least one month without pain.

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

Recurrent pain: Pain that has occurred at least 2 times over the past 12 months with each episode lasting at least 24 hours, and with a pain intensity of >2 on an 11-point numeric rating scale (>20mm on a 100mm visual analog scale), and with at least a 30-day pain-free period between episodes.

Flare-ups/Exacerbations: A flare-up (exacerbation) is a worsening of a patient's condition lasting from hours to weeks that generally impacts usual activities and/or emotions and is difficult to tolerate with the use of self-care strategies alone. A flare-up is characterized by significantly increased pain and/or other symptoms and/or pain-related functional limitations, which are equivalent to a clinically meaningful difference on standardized outcome measures.

Consultative care: Brief episodes of skilled care services that take place on an "as needed" (possibly recurring) basis following the discharge of a patient from a course of planned treatment. Consultative care services may be appropriate for patients who are likely to benefit from chronic condition management, where the trajectory is best described in terms of life course vs. episodic.

Once the condition has reached MTB, it is appropriate to consider consultative care if the patient achieved <u>></u>50% improvement in at least one critical outcome (pain, function) and there are persistent clinically relevant residual symptoms (pain) and/or (functional limitations).

Consultative care should be rendered on a PRN (as needed) basis in response to a flare-up (exacerbation). Visits are not prescheduled. Any care beyond that documented as necessary consultative care would be at the option of the patient and would be considered elective care.

Consultative care may be inappropriate when it interferes with other appropriate health care, or when the risk outweighs its benefits, e.g. provider dependence, somatization, illness behavior or secondary gain. Consultative care must require the services of a skilled health care professional. See also, Skilled Care Services, UM Policy 486.

Overview

The determination of MTB is based upon several key elements:

- The timely application and recording of appropriate, valid, and reliable measures of treatment response (outcome measures)
- An adequate period of time and/or treatment trial to reasonably anticipate that meaningful clinical improvement should take place
- Assessment of clinically meaningful change
- The probability of further meaningful clinical improvement

Outcome Measurement

Measuring and reporting outcomes is an important component of clinical practice. The assessment of treatment response is critical in directing the management of individual patient care, including determinations about the likely effectiveness of continued treatment and appropriate end-points of care (American Occupational Therapy Association [AOTA]; American Physical Therapy Association [APTA]).

Standardized outcome assessment tools that are psychometrically sound provide valid and reliable data which can be used to evaluate the success of an intervention. The use of standardized assessment tools early in an episode of care establishes the baseline status of the patient. Outcomes measured periodically throughout the episode of care provide a means to quantify changes in patient status, including determinations about whether clinically meaningful progress is being realized.

Outcomes assessment includes the application of patient-reported outcomes measures (PROMs). These tools qualify the value of health care services from the perspective of attributes identified as important to the patient. PROM tools assess how patients feel and what they are able to do by asking questions in the context of a health condition. They enable the assessment of pain, function/disability and health-related quality of life. PROMs provide a means whereby individuals can self-report their status without the confounding influence of others. A patient's subjective responses to the questions/items in PROM tools can be quantified in order to make credible judgments about measurable changes in clinical status (Chiarotto et al., 2018).

A wide variety of patient-level outcome instruments have been developed for use in clinical settings; many have been evaluated and catalogued within online databases (Table 1). Commonly used pain scales include the Numeric Rating Scale and Visual Analog Scale, while physical functioning is commonly assessed using condition-specific questionnaires e.g., Oswestry Disability Index or the Roland-Morris Low Back Pain and Disability Questionnaire (Khorsan et al., 2008).

Table 1		
Outcome	Measurement	Resources

Source/Sponsor	URL
AbilityLab	Rehabilitation Measures (sralab.org)
AbilityLab	Search Rehabilitation Measures Database (sralab.org)
American Physical Therapy Association	Patient Care APTA
Chiropractic Resource Organization	OUTCOME ASSESSMENT QUESTIONNAIRES (chiro.org)
Elon University	Tests & Measures: A Resource for Pediatric Physical Therapy Practitioners (elon.edu)
COSMIN	COSMIN - Improving the selection of outcome measurement instruments
Orthopaedic Scores	Orthopaedic Scores Home Page (orthoscores.com)

The appropriate selection of outcome measurement should reflect the *à priori* development of individual patient treatment goals. Choosing the most fit-for-purpose outcome measurement tools is fundamental because using inappropriate instruments can lead to failure to detect meaningful change and/or measurement inconsistency. Typically, outcome tools are selected from among those most frequently used and recommended, having satisfactory measurement properties in the target population.

Evidence-based decision making for the optimal selection, administration, interpretation, and sharing results of outcome measures following a plan of care should take the following into consideration (Cardillo, 2014):

- Purpose of the measure e.g., applicability with treatment goals and monitoring changes over time
- Population/group for which it is suitable for use e.g., age and diagnosis
- Practicality of the procedure/process e.g., time/work burden
- Psychometric characteristics e.g., reliability, validity, responsiveness, discriminative ability
- Strengths and limitations of the measurement tool or approach e.g., associated costs (licensing fee and equipment/resources), scientific rigor, training requirements, etc.

Global rating scales are typically used to aid in the interpretation of standardized outcome measures. While these scales lack the psychometric rigor of most standardized outcome measures, global ratings make intuitive sense in that they ask individual patients to provide measurable data concerning their subjective judgments about the meaning of change e.g., improvement (Hurst & Bolton, 2004). Global ratings that convey responses of "much improved" and "very much improved" are broadly interpreted as clinically meaningful (Dworkin et al., 2008; Hurst & Bolton, 2004; Ostelo & de Vet, 2005).

Global Attainment Scaling (GAS) represents a quantifiable method of assessing the extent to which patient's individual goals are achieved (outcomes) in the course of the intervention. In effect, GAS results in each patient having their own outcome measure, with it scored in a standardized way as to allow judgements about treatment effectiveness (Table 2). Goals may be weighted to take account of their relative importance, which allows for the calculation of composite GAS scoring as an outcome measure (Turner-Stokes, 2009).

Table 2
GAS 5-point Rating Scale

Rating	Goal attainment level	Description
-2	Much less than expected outcome	Non-clinically relevant changes in performance ranging from regression to no/minor change during the intervention period
-1	Less than expected outcome	Performance that is clinically relevant but somewhat less than expected for the intervention period
0	Expected outcome after intervention	Performance to the extent anticipated at the initiation of the treatment plan for the given intervention period
+1	Greater than expected outcome	Performance that indicates more progress than expected during the intervention period
+2	Much greater than expected outcome	Performance reflects significantly more progress than expected during the intervention period

Treatment Response

An understanding of treatment response and recovery patterns assists in the timely identification of progress towards goals, assessment of treatment effect, and identification of end-points in care due to maximum therapeutic benefit.

Progress toward goals can be assessed at points in time following the index visit when there is a substantiated basis for anticipating meaningful clinical change. These "recovery milestones" represent points in care for follow-up assessment. The recommendations from clinical guidelines and the analyses of systematic reviews provide a framework for the appropriate timing of the first assessment of a patient's response to treatment. Clinical practice guidelines encompassing a broad range of interventions for a variety of spinal, upper, and lower extremity conditions most commonly recommend assessment for clinical improvement within 4-6 weeks following the initiation of an episode of care (Table 3).

Table 3
Timing of First Outcome Assessment Following Baseline Evaluation

Source/Author (date)	Condition or Region	Timing of Assessment (mean/median [range])	Interventions
AAOS (2021)	Knee OA	8 weeks [4-8 weeks]	Exercise, manual therapy, physical agents, massage
ACP/APS (2017)	Low back pain	4 weeks	Broad range of skilled therapy services
ASSET (2010)	Shoulder surgery	6 weeks (end of phase 1 of rehabilitation schedule)	Post-operative rehab therapy
Barton (2015)	Patellofemoral pain	6 weeks [4 – 8 weeks]	Taping, exercise, foot orthoses
CCGPP (2016)	Low back pain (acute/subacute/chronic)	2-4 weeks	Scope of services provided by chiropractors
Chen (2016)	Stroke (balance)	5 weeks [2–8 weeks]	Sling exercise training
Gross (2015)	Mechanical neck disorders	6 weeks (short-term follow up = 1 day-12 weeks)	Exercise, manual therapy, acupuncture, traction, cervical support collar/pillow, guided movement
Liddle (2015)	Low back pain and pelvic pain during pregnancy	4 weeks [1 day-16 weeks]	Exercise, manual therapy, acupuncture, taping, pelvic belt, yoga, progressive relaxation, TENS
Paige (2017)	Low back pain (acute)	2 weeks [3–35 days]	Spinal manipulative therapy (SMT) compared to a broad range of interventions and controls
Royal Dutch Society for Physical Therapy (2018)	Neck pain	3 weeks (pain) 6 weeks (disability)	Broad range of skilled therapy services
Saragiotto (2016)	Low back pain (chronic)	4–10 weeks	Motor control exercised compared to other types of exercise

Skoffer (2015)	THA and TKA	7 weeks [4-9 weeks]	Post-surgical rehabilitative progressive resistance exercise
Steuri (2017)	Shoulder impingement	4 weeks [2-8 weeks]	Broad range of non- interventional and interventional services
Vickers (2017)	Chronic headache, back and neck pain, osteoarthritis, and shoulder pain	4 weeks	Acupuncture
Xu (2017)	Knee OA	4 weeks [2-8 weeks]	Manual therapy

In addition to information gleaned from guidelines and systematic reviews, research using latent class analysis (LCA) - a statistical technique that can be applied to the reporting of PROMs – has been able to determine different trends in areas such as quality of life and joint functioning, and their associated demographic and clinical features in patients recovering from elective orthopedic surgical interventions (Golinelli et al., 2023). Downie and colleagues (2016) analyzed pain scores over 12 weeks for 1585 patients with acute low back pain presenting to primary care to identify distinct pain trajectory groups and baseline patient characteristics associated with membership of each cluster. They found patients with longer pain duration were more likely to experience delayed recovery or nonrecovery. Belief in greater risk of persistence was associated with nonrecovery but not delayed recovery. Identification of discrete pain trajectory groups offers the potential to better manage acute low back pain.

While most research on measuring recovery patterns in musculoskeletal disorders has been centered on people with pain in specific anatomical pain sites, common recovery patterns or trajectories of pain and function over time have been identified. de Vos Andersen et al., (2017) evaluated a broad range of musculoskeletal conditions affecting the trunk and upper and lower extremities. The primary pain site diagnosis had little influence on the ability to assess a satisfactory outcome. The trajectory of improvement on the outcomes of pain intensity, disability and sick leave (temporary health-related income support) was similar to those previously observed in low back pain and exceeded a common threshold of clinically relevant important change (i.e., > 30% improvement from baseline).

Trajectories of neck and low back pain have been most commonly investigated. Ninety percent of patients with neck pain or low back pain presenting to chiropractors were shown to have a 30% improvement within 6 weeks. Seventy four percent of individuals with neck pain experienced a 30% reduction in pain within 3 weeks of starting care. These individuals were classified as 'recovering from mild baseline pain'. Almost sixty percent of those with low back pain, all classified as 'recovering from mild baseline pain', demonstrated a 30% reduction in pain within 3 weeks (Ailliet et al., 2018). A review of trajectory studies for low back pain by Axen et al. (2013) showed that early clinically meaningful improvement was common across all subgroups regardless of long-term recovery patterns. The 'typical' trajectory demonstrated definite improvement within in the first 5–6 weeks of a care episode.

Assessing Clinical Change

A critical consideration in the determination of MTB is the assessment of clinical importance or meaningfulness of change in scores that occurs during an episode of care. It is broadly recognized that patients' perspectives are essential in making clinical decisions and judging the results of treatment (Ostelo & de Vet, 2005). There are no objective biological markers for assessing patient-important outcomes such as pain intensity or functional limitations. Consequently, the most accurate and reliable method for detecting clinically meaningful change is based on the interpretation of PROMs. However, it is difficult to interpret changes in PROM scores since they lack an absolute

reference standard, and there is wide inter-person variability in self-reports of symptoms and function. Therefore, it is important to interpret PROMs using their MCID, which can be used as a criterion for assessing the beneficial effects of a therapy. (Salaffi et al., 2004).

The minimum clinically important difference (MCID) was first defined in 1989 as "the smallest difference in score in the domain of interest which patients perceive as beneficial" (Jaeschke et al., 1989). While others have described similar terms (e.g., minimal clinically important change) and definitions, the fundamental idea has remained the same: MCID is a calculated threshold value in an outcome of interest that patients and clinicians perceive as clinically meaningful, i.e., a value that demonstrates an appreciable change in outcome (Chung et al., 2017). According to Kirwan (2001), the basis for quantification and standardization of MCID is to minimize the variability in clinician judgment of patient 'change' following treatment. The inaccurate assessment of 'change' has been shown to mitigate the quality of clinician decision-making (Saintonge et al., 1988).

An international panel of experts has stated that 30% change from baseline may be considered a clinically meaningful improvement when comparing before and after patient-reported outcomes scores. The minimal [clinically] important change values adopted by the VII International Forum on Primary Care Research on Low Back Pain (Amsterdam, June 2006) are: 15/100 for the Visual Analogue Scale (VAS), 2/10 for the Numerical Rating Scale (NRS), 5/24 for the Roland-Morris Disability Questionnaire (RMDQ), 10/100 for the Oswestry Disability Index (ODI), and 20/100 for the Quebec Back Pain Disability Questionnaire QBPDQ) (Ostelo et al., 2008). MCID for the most common outcome assessment tool are shown in Table 4.

Table 4
MCID for Commonly Employed Outcome Measures

Author (date)	Domain	Outcome Tool	Study Characteristics	MCID	Follow Up Period
Beaton (2001)	Function/disability	DASH	N=200 Diverse subject group with either wrist/hand or shoulder problems	15 scale points	3 months
Binkley (1999)	Function/disability	LEFS	N=107 Convenience sample from 12 PT outpatient clinics All LE conditions included Correlated with SF-36 physical function score	9 scale points	1-2 days following baseline then weekly x 4 weeks
Farrar (2001)	Pain	NRS	N=2724 Retrospective analysis of controlled trials for diabetic neuropathy, post-herpetic neuralgia, chronic LBP, fibromyalgia, osteoarthritis	30% change from baseline	5-12 weeks
Fritz (2001)	Function/disability	ODI	N=67 Work-related LBP with and without LE pain	6%	4 weeks

Hagg (2003)	Pain	VAS	N=289 RCT Chronic LBP with or without LE complaints Surgical and nonsurgical treatments	18–19-point change in 100mm scale	2 years
Hagg (2003)	Function/disability	ODI	N=289 RCT Chronic LBP with or without LE complaints Surgical and nonsurgical treatments	10%	2 years
MacDermid (2009)	Function/disability	NDI	Systematic review: <i>N</i> =37 primary studies, 3 reviews, and 1 in-press paper were analyzed Rankings of quality and descriptive syntheses were performed	10% for uncomplicated neck pain 20% for cervical radiculopathy	Varied
Meade (1986)	Function/disability	ODI	N=50 RCT	8%	Weekly x 6 weeks
Stratford (1999)	NDI	N=49 Convenience sample from multiple PT outpatient clinics Eligibility criteria not described	10%	1 – 3 weeks	
Taylor (1999)	ODI	N=318 LBP with and without sciatica Surgical and nonsurgical cases 75% chronic	16.3%	Patients receiving PT and/or injections = 2 months Surgical patients = 6 months All at 12 and 24 months	
Turner	VAS	N=1124 telephonic survey	Baseline was at least 5/10 then a 2 point change	N/A	

Note. DASH = disabilities of arm, hand, and shoulder scale; LEFS = lower extremity functional scale; NRS = numerical rating scale; ODI = Oswestry disability index (revised); VAS = visual analog scale; NDI = neck disability index.

Factors that have been shown to influence MCID include the duration and severity of complaints at the initial visit (index visit), and the timing of data collection. In general, acute presentations require a larger difference between baseline and subsequent assessments to be viewed as meaningful. For example, according to Ostelo & de Vet (2005), "If a numerical rating scale (NRS) is used it seems reasonable to suggest that the MCIC [MCID] should at least be 3.5 and 2.5 for patients with acute and chronic low back pain, respectively." Similarly, patients who present with low levels of pain or disability at the index visit would need lesser changes at follow-up for MCID to be achieved

(MacDermid et al., 2009; Taylor et al., 1999; Binkley et al., 1999). Additionally, the time interval between outcome assessments may influence the magnitude of change. In general, longer time periods in comparison to lesser intervals (6 weeks vs. 2 weeks) between measurements would be expected to demonstrate greater change scores (Beaton, 2000).

Global perceived effect (GPE) is a retrospective outcome measure for musculoskeletal conditions to determine directly how much the patient perceives his or her condition to be improved. These scales require the patient to state by how much their condition has improved at time points throughout and at the end of the intervention. Most GPE scales capture multiple distinct domains relevant to "improvement" or "recovery" of one's condition such as activities of daily living, biomechanical performance, and self-efficacy (Evans et al., 2014). Various GPE scales have been described in the literature. The 7-point GPE scale has emerged as a commonly used measure for the direct reporting of condition improvement (Beurskens et al., 1996). Physical outcomes and PROMs have shown a relationship with GPE scales (Fritz & Irrgang, 2001). Several authors have demonstrated, on a 7-point GPE scale, category six or 'much better or improved' represents the threshold for clinically important improvement (Beurskens et al., 1996; Eversden et al., 2007; Farrar et al., 2001; Lauridsen et al., 2006; Ostelo et al., 2004; Pool et al., 2007; and van der Roer et al., 2006). Kamper and colleagues (2010) sought to validate the test-retest reliability and construct validity of the GPE scale in patients with musculoskeletal disorders. Analyzing data from seven different studies including patients with whiplash-associated disorder, low back pain, post-operative low back pain, shoulder pain, and ankle pain, investigators found test-retest reliability scores were high, indicating clinicians administering a scale could be reasonably confident that random error did not compromise GPE ratings. They further discovered current status is likely a strong influence when patients rate GPE and observed this tendency increased as the transition time period lengthened.

It has been recommended that the selection of measures should be composed of a retrospective method (GPE scale) and prospective methods (pain and functional questionnaires), in order to classify patients as either clinically improved or clinically not-improved (Beurskens et al., 1996). This approach to interpreting PROMs can be applied to the determination of MTB.

Assessing the Probability of Further Meaningful Improvement

The probability of further meaningful improvement ties into the three preceding elements for assessing maximum therapeutic benefit (MTB). Further meaningful improvement can occur only when there is a potential for MCID. Standardized outcome measures provide the template for identification of MCID. The timing of assessment should be consistent with realistic expectations i.e., short-term goals. Judgments about the probability of further meaningful clinical improvement with ongoing treatment can be informed by research describing factors associated with the patterns of improvement and the longitudinal trajectories of a condition.

Artus and colleagues (2010) systematically assessed patterns of pain and functional improvement in individuals diagnosed with nonspecific low back pain. The review included a wide variety of treatments ranging from simple advice to intensive multidisciplinary rehabilitation pain management programs including examples such as medications, acupuncture, chiropractic, and transcutaneous electrical nerve stimulation (TENS). There was a similar pattern of initial rapid improvement at 6 weeks; after which, only small further improvements for both pain and functional disability were seen regardless of the intervention. A subsequent systematic review and meta-analysis of randomized clinical trials and observational studies examined the course of non-specific low back pain. The results were no different: a rapid improvement in the first 6 weeks followed by a smaller further improvement (Artus et al., 2014).

A simple clinical prediction model – assessed after the first week of an episode of care for low back pain – has been shown to reliably inform determinations about the probability of further clinically meaningful improvement for individual patients (da Silva et al., 2019). This model uses five variables: duration of current episode, number of previous episodes, depression score, baseline pain intensity, and magnitude of change in pain level at 1-week. This

information has been shown to be able to predict, after 1 week of care, the likelihood of further clinical improvement (recovery) from an episode of acute LBP at 1 month and 3 months. This prediction model is consistent with a previous study by Hancock et al. (2009) that reported pain intensity, duration of pain and number of previous episodes as important factors in predicting further treatment response. Further, the application of this model performed better than clinicians' judgment in predicting treatment response.

For acute and chronic non-spinal musculoskeletal pain conditions, generic factors appear to play an important role in assessing the probability of further MCID, regardless of the location of pain (Henschke et al., 2012). Generic factors predicted outcome over different time periods (3 months and 12 months) and for both acute and chronic non-spinal musculoskeletal pain. The most consistent predictors of poor outcome were having had the same complaint in the previous year, a lower level of education, lower scores on the Short Form 36 vitality subscale, using pain medication at baseline, and being bothered by the complaint more often in the past 3 months.

Other studies have investigated the predictive ability of more discrete variables. A ≥2 point change (on an 11-point numeric rating scale) from baseline to after the second physical therapy visit was associated with further positive outcomes (pain and function) in patients who receive a manual therapy approach (Cook et al., 2012). Similarly, Peterson and colleagues (2012) showed that patients with low back pain undergoing chiropractic treatment, who are likely to respond to further care, demonstrate early improvement. Patients with chronic and acute pain reporting that they were "much better" or "better" on the Patient Global Impression of Change scale at 1 week after the first chiropractic visit were 4 to 5 times more likely to be improved at both 1 and 3 months compared with patients who were not improved at 1 week. Patients with acute pain reported more severe pain and disability initially but recovered faster. Patients with chronic and acute back pain both reported good outcomes, and most patients with radiculopathy also improved.

Another component in the determination of MTB, as it relates to the potential for further meaningful improvement, is the consideration of end-points for skilled professional services. Skilled care may be necessary: 1) to improve a patient's current condition; 2) to prevent or slow further deterioration of the patient's condition; or 3) to help a person keep, learn, or improve skills and functioning for daily living to maintain the patient's current condition. A determination that MTB has been reached from the skilled services of a qualified health care provider is appropriate, when none of these conditions are met and/or recovery milestones are reached and progress toward goals is such that outcome measures approximate normative data for asymptomatic populations or are indicative of mild deficits, which can typically be managed through a general exercise program or other self-care (Brennan et al., 2006; Liebenson, 2007; Roland & Fairbank, 2000).

Consultative Care

Consultative care (chronic condition management or supportive care) may be appropriate for individuals who were discharged from continuing skilled care services after reaching MTB and are subsequently unable to sustain self-sufficient and independent management of his/her chronic condition (Hanson et al., 2015; Whalen et al., 2019). The medical necessity of consultative care must be documented in the patient's health care record.

Criteria that support the medical necessity of consultative care include all of the following:

- Treatment success (>50% improvement in pain and/or function) was previously achieved during the initial episode of care (Dworkin et al., 2008; Pham et al., 2003)
- Clinically relevant pain and/or functional deficits persisted after achieving MTB (Whalen et al., 2019)
- Alternative treatment options including referral were considered
- The patient was educated in appropriate post-discharge self-management approaches
- A "flare" or "recurrence" (see Definitions) has occurred
- Skilled care services are aimed at supporting a return to prior MTB outcomes
- Treatment is not considered to be maintenance care

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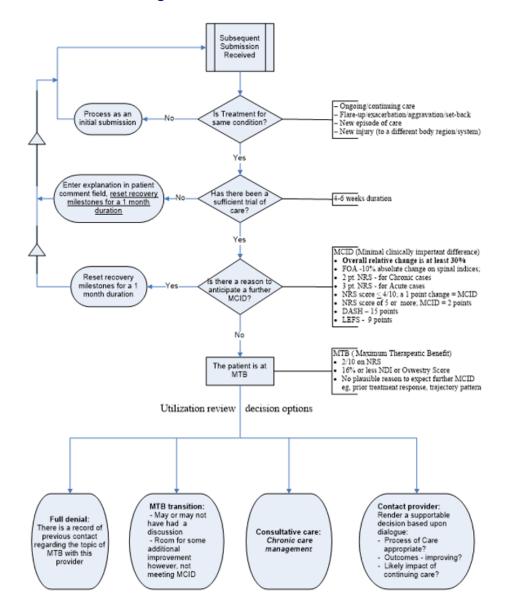
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Appendix A

MTB decision-making flow



Review and Approval History

Date	Description
7/2006	Original effective date
12/04/2006	Annual review completed
4/10/2008	Annual review completed
11/11/2008	Policy header rebranded: OptumHealth Care Solutions-Physical Health
1/15/2009	Policy placed into new format
4/30/2009	Annual review completed. MTB decision guide added
7/16/2009	Policy revised and approved by QIC; Nonspinal disorders added to cited literature; Definitions updated; References updated; Decision Guide for interpreting standardized outcomes assessment tools in the context of global ratings was added; Plain Language Summary updated
4/08/2010	Annual review completed
10/26/2010	Policy rebranded to OptumHealth Care Solutions, Inc. (Optum Health)
4/07/2011	Annual review completed
4/19/2012	Annual review completed
4/18/2013	Annual review completed
4/17/2014	Annual review completed; Policy rebranded "Optum* by OptumHealth Care Solutions, Inc."
4/16/2015	Annual review completed
4/21/2016	Annual review completed
4/20/2017	Annual review completed; Legal entity name changed from "OptumHealth Care Solutions, Inc." to "OptumHealth Care Solutions, LLC."
4/26/2018	Annual review completed; Background, Definitions, Summary sections, and MTB decision flow revised to reflect advances in the body of evidence.
4/25/2019	Annual review completed
4/23/2020	Annual review completed: Updated definition of flare-up, added consultative care criteria to the Background section.
4/22/2021	Annual review completed
5/03/2022	Annual review completed
6/29/2022	Updated legal entity name "OptumHealth Care Solutions, LLC." to *Optum™ Physical Health ("Optum") includes OptumHealth Care Solutions, LLC; ACN Group IPA of New York, Inc.; ACN Group IPA of California, Inc. d/b/a OptumHealth Physical Health of California; Managed Physical Network, Inc.; and OrthoNet Holdings, Inc. which includes OrthoNet New York IPA, Inc., OrthoNet West, Inc., OrthoNet, LLC, OrthoNet of the South, Inc.
4/27/23	Annual review and approval completed; no significant changes made to the document. Updated contact email from policy.inquiry@optumhealth.com to phpolicy_inquiry@optumhealth.com .

1/31/2024	Annual review; no substantive changes. Approved by Optum Clinical Guideline Advisory Committee
04/25/2024	Annual review and approval completed. Document content transitioned to new policy template. No significant changes made to the document.

Plain Language Summary

Determination of Maximum Therapeutic Benefit Utilization Management Policy # 84

Plain Language Summaries are presented to supplement the associated clinical policy or guideline. These summaries are not a substitute for advice from your own healthcare provider.

What is maximum therapeutic benefit and what is known about it so far?

Musculoskeletal pain, especially spinal pain is a common problem. Traditional nonsurgical treatments that are helpful for some patients with musculoskeletal pain include physical therapy, manipulation (chiropractic), exercise and drugs (pain killers, anti-inflammatory drugs, and muscle relaxants). It is important to determine if a particular treatment is helping a person improve (decreased pain and increase abilities to perform daily activities). Most treatments reach a point where no further improvement can be expected. This is called the point of maximum therapeutic benefit (MTB). MTB can be reached when complaints either fully resolve, or when pain and/or disability persist – even with ongoing treatment.

It is not difficult or burdensome to measure improvement resulting from treatment. There are enough resources available for a healthcare provider to know when and how to measure improvement. With this information, the reasonable likelihood of additional improvement can be determined.

Most healthcare benefit certificates do not include treatment that is not resulting in a reasonable expectation of further improvement from that particular treatment.

How was maximum therapeutic benefit evaluated?

A work group of clinicians was assigned to review the available research. The internet was searched for policies and articles that provided information about 1) when during the course of care is it reasonable to measure for improvement; 2) methods to measure improvement in pain and/or disability; 3) the probability of further improvement with a continuation of treatment; and 4) the likelihood that stopping treatment will result in a worsening of either pain or disability.

After gathering and analyzing this information, a policy was presented to a series of committees that included independent health care practitioners.

What did the workgroup find?

- Most individuals can expect to notice measurable improvement in pain and/or disability early during the course of care – 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.

What were the limitations of the information?

While there is increasing amount of information about nonspinal conditions e.g., shoulder, knee, ankle, etc., the majority of research is related to spinal conditions (low back and neck pain, sciatica, etc.). The timelines for improvement may not be applicable to some types of post-surgical care.

What are the conclusions?

An individual has reached MTB when after at least 4 to 6 weeks of treatment one of the following is present:

- Complaints have resolved or stabilized
- There has been improvement; however, there is no reason to expect further improvement with the same care
- There has not been improvement in pain and/or disability (based on standardized assessments)
- There is insufficient information in the healthcare record to determine that improvement has occurred

What are the options once MTB has been reached?

Once MTB has been reached it is the responsibility of the healthcare provider to:

- Revise the plan of care based upon current research evidence
- Discharge a patient from active/therapeutic care
- Recommend an alternative type of treatment by a different healthcare provider