PREFACE

This Medical Guidance is intended to facilitate the Utilization Management process. It expresses Molina’s determination as to whether certain services or supplies are medically necessary, experimental, investigational, or cosmetic for purposes of determining appropriateness of payment. The conclusion that a particular service or supply is medically necessary does not constitute a representation or warranty that this service or supply is covered (i.e., will be paid for by Molina) for a particular member. The member’s benefit plan determines coverage. Each benefit plan defines which services are covered, which are excluded, and which are subject to dollar caps or other limits. Members and their providers will need to consult the member’s benefit plan to determine if there are any exclusions or other benefit limitations applicable to this service or supply. If there is a discrepancy between this policy and a member’s plan of benefits, the benefits plan will govern. In addition, coverage may be mandated by applicable legal requirements of a State, the Federal government or CMS for Medicare and Medicaid members. CMS’s Coverage Database can be found on the following website: http://www.cms.hhs.gov/center/coverage.asp.

FDA INDICATIONS

Cognitive rehabilitation programs are not subject to regulation by the FDA.

CENTERS FOR MEDICARE AND MEDICAID SERVICES (CMS)

The coverage directive(s) and criteria from an existing National Coverage Determination (NCD) or Local Coverage Determination (LCD) will supersede the contents of this Molina medical coverage guidance (MCG) document and provide the directive for all Medicare members. The directives from this MCG document may be followed if there are no available NCD or LCD documents available and outlined below.

CMS does not have a National Coverage Determination (NCD) or a Local Coverage Determination (LCD) for cognitive rehabilitation for traumatic brain injury (TBI). ²

INITIAL COVERAGE CRITERIA

Cognitive Rehabilitation is considered not medically necessary and may not be authorized in adult and pediatric members with traumatic brain injury.

CONTINUATION OF THERAPY

N/A
Cognitive Rehabilitation is considered not medically necessary and may not be authorized in adult and pediatric members with traumatic brain injury.

**DESCRIPTION OF PROCEDURE/SERVICE/PHARMACEUTICAL**

Traumatic brain injury (TBI) is defined as an injury to the brain by externally inflicted trauma, which may result in significant physical, cognitive, and psychosocial impairment. Recovery from TBI is lengthy and variable, with a course that spans months or years. Cognitive recovery proceeds in overlapping stages, with improvement in different domains of cognitive operation occurring at different times.

Cognitive rehabilitation is a program of systematic, functionally oriented service of therapeutic activities based on assessment and understanding of the patient’s brain-behavioral deficits and includes therapies that are designed to improve damaged intellectual, perceptual, and behavioral skills, and to increase levels of self-management and independence following damage to the central nervous system. This therapy is directed toward brain-behavior deficits, such as attention, memory and learning, affect and expression, and executive functions. The treatment is designed to help improve damaged intellectual, perceptual, and behavioral skills, as opposed to sensorimotor skills or strictly emotional function. Cognitive rehabilitation interventions achieve functional changes by: reinforcing, strengthening, or reestablishing previously learned behavior patterns; establishing new patterns of cognitive activity through compensatory mechanisms in damaged brain areas; or establishing new patterns of cognitive activity through use of external compensatory mechanisms such as personal orthoses or other devices. The goals of cognitive rehabilitation are to improve the patient’s capacity to process and interpret information and function in family and community life while maximizing their degree of return to their previous level of functioning.

Cognitive rehabilitation programs are administered either in the home or in an institutional setting, such as a trauma unit or rehabilitation center, transitional living or day treatment program, or ambulatory clinic. The number and duration of treatment sessions vary widely depending on the condition of the patient and response to treatment. Most cognitive rehabilitation programs include speech pathologists and occupational therapists working with neuropsychologists. Other professionals involved in cognitive rehabilitation included recreation therapists, physical therapists, and nurses.  

**GENERAL INFORMATION**

**Summary of Medical Evidence**

*Systematic Reviews/Meta-analysis:*

Comper and associates (2005) conducted a systematic review of 20 studies to evaluate the effectiveness of interventions for mild TBI. The authors identified four treatment options for mild TBI: pharmacotherapy, cognitive rehabilitation, patient education, and other interventions. The authors also identified three studies evaluating the effects of cognitive behavioral rehabilitation for mild TBI and concluded that there is little evidence to suggest that cognitive behavioral rehabilitation is an effective treatment for patients with mild TBI.
While all three studies demonstrated improvement in neuropsychological test scores, it is unclear whether the improved scores were due to the individualized treatment methods, and the results may not be generalizable beyond the study population.  

Gordon et al. (2006) reviewed 13 studies that evaluated comprehensive-holistic cognitive rehabilitation in patients with TBI. The reviewed studies used psychological interventions to treat multiple cognitive deficits, including emotional, motivational, and interpersonal aspects of functioning. The results demonstrated improved community functioning in these patients. Because of methodological limitations, subjective outcomes, and small patient samples in the reviewed studies, the interpretation of results is inconclusive.

The Blue Cross/Blue Shield Technology Evaluation Center (TEC) reviewed the published literature on cognitive rehabilitation for TBI patients. The focus was on randomized controlled studies involving at least 8 patients and using comprehensive, validated instruments to measure function. The main finding from the report was that most of the randomized studies do not show an improvement in health outcomes after cognitive rehabilitation. The one nonrandomized study reporting improvement in health outcomes was limited by baseline differences in types of patients enrolled in the two groups and lack of long-term follow-up. The authors concluded that the randomized trial literature does not provide strong evidence for the efficacy of cognitive rehabilitation in the treatment of TBI. Prospective randomized designs using validated measures of health outcomes are needed to demonstrate the effectiveness of cognitive rehabilitation as either an integrated holistic program or as a separable component to treat a specific deficit.

Kennedy et al. (2008) conducted a systematic review and meta-analysis of 15 studies that evaluated interventions designed to address deficits of executive function following TBI. A total of 10 studies, including 5 RCTs, used step-by-step metacognitive strategy instructions (MSI) to treat with executive function deficits. Results from the meta-analysis of the five RCTs of MSI, as well as the findings from the other studies of MSI, led the authors to conclude that there is sufficient evidence to recommend that MSI be used in young to middle-aged adults with TBI to achieve improvement in everyday, functional problems.

The systematic review by Cicerone et al. (2009) was based on the earlier systematic reviews from the Brain Injury Interdisciplinary Special Interest Group of the American Congress of Rehabilitation Medicine (Cicerone et al., 2000; Cicerone et al., 2005). Cicerone et al. (2009) evaluated the methodological quality of 53 comparative effectiveness studies (32 RCTs and 21 observational studies) involving exclusively or primarily participants with TBI. Methodological quality was assessed by adapting criteria from prior reviews of rehabilitation research. The authors concluded that several high-quality RCTs support the effectiveness of therapies for attention, communication skills, and executive functioning following TBI. In addition, the authors noted that several high-quality observational studies provide evidence of the effectiveness of comprehensive-holistic rehabilitation after TBI, including improvement in participation outcomes.
ECRI (2009) performed a health technology assessment on cognitive rehabilitation for TBI that included a systematic review with meta-analyses. This report included 18 studies; the overall quality of the studies that composed the evidence base was moderate. The following conclusions were presented in this report:

- Adults with moderate to severe TBI who undergo social skills training score significantly better on measures of social communication than patients who receive no treatment.
- Adults with TBI who receive comprehensive-holistic cognitive rehabilitation report significant improvement on QOL measures relative to those who undergo less intense therapy.

The authors note that these conclusions were based on meta-analyses of two small studies of moderate quality; thus, they rated the strength of evidence for these conclusions as low. The authors were unable to draw definitive conclusions about the effectiveness of cognitive rehabilitation to treat deficits of attention, memory, visuospatial ability, executive function, and multiple domains of cognitive functioning. Several factors contributed to the lack of conclusions for these areas, including differences in the outcomes assessed in the studies, insufficient number of studies addressing an outcome, or inconclusiveness of meta-analytic results.

Rohling et al. (2009) conducted a meta-analysis of the cognitive rehabilitation literature previously reviewed by Cicerone et al. (Ciccone et al., 2000; Cicerone et al., 2005). The analysis found a small, significant treatment effect size (ES=0.30), directly attributable to cognitive rehabilitation, after controlling for improvement in nontreatment control groups. Treatment effects were moderated by the cognitive domain targeted by treatment, time since injury, type of brain injury, and age. The authors concluded that the meta-analysis provided sufficient evidence for the effectiveness of attention training after TBI and language, and visuospatial training for aphasia and neglect syndromes after stroke.

Snell et al. (2009) performed a systematic review of psychological/neuropsychological interventions for adults with mild TBI. Of the three studies included in this review, only one reported a small treatment effect on the Community Integration Questionnaire in favor of cognitive rehabilitation. The authors conclude that the evidence regarding the effectiveness of cognitive rehabilitation for mild TBI remains inconclusive.

Cicerone et al. (2011) conducted an update of the Brain Injury Interdisciplinary Special Interest Group of the American Congress of Rehabilitation Medicine for cognitive behavioral rehabilitation of people with TBI and stroke based on literature from 2003 to 2011. This update assessed 112 studies of cognitive rehabilitation following TBI or stroke; the authors recommended two new practice standards and the strengthening or refinement of several practice standards issued in the past. This review, along with the two prior reviews (Cicerone et al., 2000; Cicerone et al., 2005), has resulted in evaluation of 370 interventions (65 class I or Ia, 54 class II, and 251 class III studies) that provide evidence regarding the comparative effectiveness of cognitive rehabilitation. The authors note that of the 65 class I and Ia studies, there were 15 comparisons (with
550 participants) of cognitive rehabilitation to no active treatment, and cognitive rehabilitation was of benefit for every one of these comparisons. There were also 17 comparisons (involving 696 participants) of cognitive rehabilitation and conventional rehabilitation, and the authors indicate that cognitive rehabilitation was of greater benefit in 94.1% of these comparisons. The authors conclude that there is substantial evidence to support interventions for attention, memory, social communication skills, executive function, and comprehensive-holistic neuropsychologic rehabilitation after TBI. The authors note that their systematic reviews are consistent with the view that cognitive rehabilitation is effective for helping patients to learn and apply compensations for residual cognitive limitations, but these reviews provide more limited evidence regarding the efficacy of cognitive rehabilitation to improve functional activities, community participation, or life satisfaction in patients with TBI.  

**Randomized Controlled Trial:**

Spikeman and colleagues (2010) performed a multicenter randomized control trial (RCT) to evaluate the effects of a treatment for dysexecutive problems after acquired brain injury (ABI) on daily life functioning. Seventy-five ABI patients were randomly allocated to either the experimental treatment, multifaceted strategy training for executive dysfunction, or a control treatment, computerized cognitive function training. Assessment took place before, directly after, and 6 months post-treatment. The primary outcome measure, the Role Resumption List (RRL), and two other follow-up measures, the Treatment Goal Attainment (TGA) and the Executive Secretarial Task (EST), were indications of daily life executive functioning. The experimental group improved significantly more over time than the controls on the RRL and attained significantly higher scores on the TGA and EST. We conclude that our treatment has resulted in significant improvements of executive functioning in daily life, lasting at least 6 months post-treatment. Although control patients' satisfaction and subjective well-being were at the same level, the experimental group had better abilities to set and accomplish realistic goals, to plan, initiate, and regulate a series of real-life tasks, and to resume previous roles with respect to work, social relations, leisure activities, and mobility.

Ownsworth and associates (2008) performed a randomized controlled trial to study the comparison of individual, group and combined intervention formats for improving goal attainment and psychosocial function following acquired brain injury. Thirty-five participants with a mean time of 5.29 years (standard deviation = 3.9) since acquired brain injury were randomly allocated into 6 groups involving an intervention or waiting list control condition for 1 of 3 intervention formats. Interventions were 3 h/week for 8 weeks. Formats included: group-based support (n = 12), individual occupation-based support (n = 11), and a combined group and individual support intervention (n = 12). Participant outcomes were examined at pre-, post-, and 3-month follow-up assessment on the Canadian Occupational Performance Measure, Patient Competency Rating Scale, and Brain Injury Community Rehabilitation Outcome 39 Scales. Overall, the findings indicated that the individual intervention component appeared to contribute particularly to gains in performance in goal-specific areas. The combined intervention was associated with maintained gains in performance and satisfaction. However, gains in behavioural competency and psychological well-being were more likely to occur after the group and individual interventions. The authors concluded that these findings generally support the efficacy of
brief intervention formats following acquired brain injury, although further research is needed to examine clients’ suitability for particular interventions.  

Zhu et al (2007) evaluated the effects of an increase in the intensity of rehabilitation on the functional outcome of patients with traumatic brain injury (TBI). Sixty-eight patients (age 12-65 years) with moderate-to-severe TBI were included. They were randomized into high (4-hour/day) or control (2-hour/day) intensity rehabilitation programmes at an average of 20 days after the injury. The programmes ended when the patients achieved independence in daily activities or when 6 months had passed. No significant differences were found in the Functional Independence Measure (FIM) (primary outcome) and Neurobehavioural Cognitive Status Examination (NCSE) total scores between the two groups. There were significantly more patients in the high intensity group than in the control group who achieved a maximum FIM total score at the third month (47% vs. 19%, p = 0.015) and a maximum Glasgow Outcome Scale (GOS) score at the second (28% vs. 8%, p = 0.034) and third months (34% vs. 14%, p = 0.044). The authors note that early intensive rehabilitation may improve the functional outcome of patients with TBI in the early months post-injury and hence increase the chance of their returning to work early. Intensive rehabilitation in this study speeded up recovery rather than changed the final outcome.  

Comparison Study:

Doig and colleagues (2011) sought to determine the effectiveness of a goal-directed, environment-focused occupational therapy intervention and to compare rehabilitation gains across a day hospital (outpatient) setting and home setting. Descriptive and non-parametric comparative analyses employed. Fourteen participants with severe traumatic brain injury completed a 12 week outpatient occupational therapy programme. The programme was directed by the participant's chosen goals, which were established using a client-centred, structured, goal-planning process. Outcome measures included Goal attainment scaling, the Canadian Occupational Performance Measure, the Sydney Psychosocial Reintegration Scale, the Mayo-Portland Adaptability Index, the Craig Hospital Inventory of Environmental Factors and self-rated satisfaction with therapy. Main outcomes and results: The therapy programme resulted in significant improvements in goal attainment, occupational performance, psychosocial reintegration and ability and adjustment levels, compared with baseline. Differences in gains made in home vs day hospital settings were not statistically significant, with the exception of higher levels of patient satisfaction with therapy at home. The authors noted that further research is needed to compare the outcomes and determine the cost effectiveness of therapy at home and in day hospital settings to assist further with decision-making about where to conduct therapy.  

Hayes, Cochrane, UpToDate, MD Consult etc.

Hayes has a Medical Technology Directory Report (updated 2013) entitled Cognitive Rehabilitation for Traumatic Brain Injury.  

This report outlines that there is some evidence of efficacy for cognitive rehabilitation for memory or social skills. There is also some evidence that comprehensive-holistic cognitive rehabilitation
improves community integration compared with standard neurorehabilitation therapy. However, due to the variation among studies in targeted domains and rehabilitation protocols, and the variation in type and severity of injury and impairment in TBI, no strong conclusions can be drawn at this time regarding the efficacy of cognitive rehabilitation. None of the reviewed studies reported safety issues. Therefore, the use of cognitive rehabilitation in adults with TBI has a potential but unproven benefit and the use of cognitive rehabilitation in children and adolescents with TBI there is no proven benefit based on a paucity of evidence in the peer reviewed medical literature.

UpToDate:

In a report entitled Postconcussion syndrome the authors indicate that treatment for postconcussion syndrome is based on symptoms and the most common complaints include headache, dizziness, cognitive impairment, and psychological symptoms. Treatment for this disorder may include migraine medications, analgesics, psychological counseling, and/or psychotropic medications as dictated by patient complaints and disability (Grade 2C). Education and reassurance shortly after the injury are also suggested. The use of cognitive retraining for cognitive difficulties after mild head injury is controversial. Because cognitive rehabilitation can be quite costly, prospective studies are needed demonstrating efficacy before widespread application can be recommended. Simple techniques, such as training in the use of a notebook and visual imagery may be helpful for patients who have memory impairments.

Professional Organizations

American Congress of Rehabilitation Medicine (ACRM): A systematic review by the Brain Injury – Interdisciplinary Special Interest Group of the ACRM concluded that there is some evidence of the effectiveness of several forms of cognitive rehabilitation for persons with TBI. This paper made specific recommendations for remediation of attention, memory, functional communication, and executive functioning after TBI. Details of these recommendations are provided in RELATED ISSUES, Systematic Reviews Published Prior to 2001. An update of this review found that there was evidence to recommend two new practice standards and strengthen or refine several practice standards that had been advanced previously. The authors concluded that there is sufficient information to support evidence-based clinical protocols, and design and implement a comprehensive program of empirically supported therapies for cognitive disability after TBI and stroke.

National Academy of Neuropsychology (NAN): In a 2002 position statement, NAN expressed support for empirically based and rationally based cognitive rehabilitation techniques that are designed to improve the quality of life and functional outcomes for patients with acquired brain injury. This statement also outlined the need for more evidence-based research to define cost-effective cognitive rehabilitation interventions.
National Institute of Neurological Disorders and Stroke (NINDS): 6 In 2004, a NINDS workshop consisting of three interdisciplinary teams established a guideline for accelerated progress in cognitive interventions for stroke, TBI, and brain tumor patients. The goal of the workshop was to promote the use of evidence-based interventions in the evaluation, treatment, and assistance of patients with disorders of the brain affecting higher thought processes such as working memory, attention, and executive function. The workshop made several recommendations for future trials, including: development of tools that are standardized, sensitive, and reliable to assess deficits and predict outcomes; development of a step-wise implementation plan for interventions once they are established; and development of a more appropriate clinical trials model specifically for brain tumor, stroke, and TBI populations.

European Federation of Neurological Societies (EFNS): 7 In 2005, the cognitive rehabilitation task force of EFNS provided an updated statement and recommendations for neurological practice to evaluate the clinical effectiveness of cognitive rehabilitation for TBI and stroke patients. The task force concluded that: (1) the current evidence from studies is inconclusive due to poor research methodological quality, insufficient sample size, failure to compare treatment methods, and inability to determine the outcome at the disability level; and (2) there is a need for adequately designed randomized clinical trials with patient homogeneity and treatment standardization to evaluate the efficacy of cognitive rehabilitation for TBI.

New Zealand Guidelines Group (NZGG): 8 In July 2006, NZGG published a guideline on diagnosis, acute management, and rehabilitation following TBI. This guideline set forth several recommendations pertaining to cognitive rehabilitation, including the following:

- Specialist advice should be sought when cognitive impairment is causing management difficulties or limiting the response to rehabilitation (Grade C).
- People with persistent cognitive deficits following traumatic brain injury should be offered functionally oriented cognitive rehabilitation (Grade B).
- Cognitive rehabilitation should include:
  - In the acute phase, management in a structured and distraction-free environment and targeted programs for those with executive difficulties (Grade A).
  - Attempts to improve attention and information-processing skills (Grade B).
  - Teaching compensatory techniques (Grade C).
  - The use of external memory aids (Grade A).
  - Trial-and-error learning should be avoided in people with memory impairment (Grade B).
- Grades reflect the strength of the supporting evidence, rather than the importance of the recommendations.
National Institute for Health and Clinical Excellence (NICE): \textsuperscript{9} UK-based NICE issued an updated guideline on triage, assessment, investigation, and early management of head injury in infants, children, and adults in September 2007. The guideline provides best practice recommendations for the care of all patients who present with a suspected or confirmed traumatic head injury with or without other major trauma. Rehabilitation and long-term care of patients with head injury are not addressed in this guideline.

Defense Centers of Excellence (DCoE) for Psychological Health and Traumatic Brain Injury and the Defense and Veterans Brain Injury Center (DVBIC): \textsuperscript{10} The DCoE for Psychological Health and Traumatic Brain Injury and DVBIC established a steering committee consisting of members with expertise in TBI nursing, neurology, family practice, neuropsychology, occupational therapy, speech-language pathology, research, and psychiatry. The committee concluded that a consensus conference was required to develop a guidance document for these services. The conference met over a period of 2 days in April 2009 and drafted consensus-based recommendations using existing evidence-based reviews and expert clinical knowledge and experience from current cognitive rehabilitation programs within the Department of Defense, Department of Veterans Affairs, and in the civilian communities. These recommendations address issues such as assessment, intervention, outcomes/efficacy, and program implementation as they pertain to cognitive rehabilitation following mild TBI.

Department of Veterans Affairs and Department of Defense (VA/DOD): \textsuperscript{11} In April 2009, the VA/DOD issued a clinical practice guideline pertaining to the management of concussion/mild TBI. This guideline recommended that individuals who present with memory attention, and/or executive function problems that did not respond to initial treatment (e.g., reassurance, sleep education, or pain management) may be considered for referral to cognitive rehabilitation therapists with expertise in TBI (e.g., speech and language pathology, neuropsychology, or occupational therapy) for compensatory training and/or instruction and practice on use of external memory aids such as a personal digital assistant. These recommendations received strength of recommendation ratings of C. For the C rating, no recommendation for or against the routine provision of the intervention is made and at least fair evidence was found that the intervention can improve health outcomes, but the balance of benefits and harms is too close to justify a general recommendation.

Scottish Intercollegiate Guidelines Network (SIGN): \textsuperscript{12} In May 2009, SIGN published a guideline on the early management of patients with a head injury. This guideline focuses on the follow-up of people admitted to the hospital for up to 72 hours. SIGN recognizes that head injuries can cause a wide variety of issues beyond the first 72 hours, but detailed advice on treatment and rehabilitation is beyond the scope of this guideline.

**CODING INFORMATION**

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**RESOURCES REFERENCES**


