COGNITIVE REHABILITATION

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INSTRUCTIONS FOR USE

This Medical Policy provides assistance in interpreting UnitedHealthcare benefit plans. When deciding coverage, the member specific benefit plan document must be referenced. The terms of the member specific benefit plan document [e.g., Certificate of Coverage (COC), Schedule of Benefits (SOB), and/or Summary Plan Description (SPD)] may differ greatly from the standard benefit plan upon which this Medical Policy is based. In the event of a conflict, the member specific benefit plan document supersedes this Medical Policy. All reviewers must first identify member eligibility, any federal or state regulatory requirements, and the member specific benefit plan coverage prior to use of this Medical Policy. Other Policies and Coverage Determination Guidelines may apply. UnitedHealthcare reserves the right, in its sole discretion, to modify its Policies and Guidelines as necessary. This Medical Policy is provided for informational purposes. It does not constitute medical advice.

UnitedHealthcare may also use tools developed by third parties, such as the MCG™ Care Guidelines, to assist us in administering health benefits. The MCG™ Care Guidelines are intended to be used in connection with the independent professional medical judgment of a qualified health care provider and do not constitute the practice of medicine or medical advice.

BENEFIT CONSIDERATIONS

Before using this policy, please check the member specific benefit plan document and any federal or state mandates, if applicable.

Essential Health Benefits for Individual and Small Group

For plan years beginning on or after January 1, 2014, the Affordable Care Act of 2010 (ACA) requires fully insured non-grandfathered individual and small group plans (inside and outside of Exchanges) to provide coverage for ten categories of Essential Health Benefits ("EHBs"). Large group plans (both self-funded and fully insured), and small group ASO plans, are not subject to the requirement to offer coverage for EHBs. However, if such plans choose to provide coverage for benefits which are deemed EHBs, the ACA requires all dollar limits on those benefits to be removed on all Grandfathered and Non-Grandfathered plans. The determination of which benefits constitute EHBs is made on a state by state basis. As such, when using this policy, it is important to refer to the member specific benefit plan document to determine benefit coverage.

COVERAGE RATIONALE

Cognitive rehabilitation is proven and medically necessary for the treatment of traumatic brain injury (TBI) and brain injury due to stroke, aneurysm, anoxia, encephalitis, brain tumors, and brain toxins when the patient can actively participate in the program (e.g., is not comatose or a vegetative or minimally conscious state which precludes such active engagement). The treatment regimen usually includes one of the following modalities:

- Specific interventions for functional communication deficits, including pragmatic conversational skills, or
• Compensatory memory strategy training.

Cognitive rehabilitation is unproven and not medically necessary for the treatment of cerebral palsy, Down syndrome, Alzheimer's disease, attention deficit hyperactivity disorder, developmental disorders such as autism, schizophrenia and Parkinson's disease.

Evidence in the published, peer-reviewed, medical literature to support the use of cognitive rehabilitation for these conditions is limited and conflicting. Available studies also contain design flaws including small study samples, lack of comparison groups and lack of long-term follow-up.

Coma stimulation is unproven and not medically necessary for the treatment of comatose patients or patients in a vegetative or minimally conscious state who have sustained a brain injury due to limited evidence with overall poor quality in methodology and design, and diversity in reporting outcome measures.

DEFINITIONS

Coma: A state of unconsciousness from which one cannot be aroused. Coma is the most severe of the alterations of consciousness. It differs from sleep in that comatose patients will not awaken with stimulation. It differs from lethargy, drowsiness, or stupor (states in which patients are slow to respond) in that comatose patients are completely unresponsive. Finally, it differs from delirium, confusion, or hallucinosis (states in which patients' sense of reality is distorted and expressions are bizarre) in that comatose patients cannot express themselves at all (Taber's, 2014).

Minimally Conscious State: A severe alteration in consciousness that does not meet the diagnostic criteria for either coma or a persistent vegetative state, in which patients respond to some sounds and unpleasant stimuli and have a sleep-wake cycle but do not attend to their environment consistently (Taber's, 2014).

Persistent Vegetative State: A continuing and unremitting clinical condition of complete unawareness of the environment accompanied by sleep-wake cycles with either complete or partial preservation of hypothalamic and brainstem autonomic functions. The diagnosis is established if the condition is present for 1 month after acute or nontraumatic brain injury or has lasted for 1 month in patients with degenerative or metabolic disorders or developmental malformations (Taber's, 2014).

APPLICABLE CODES

The following list(s) of procedure and/or diagnosis codes is provided for reference purposes only and may not be all inclusive. Listing of a code in this policy does not imply that the service described by the code is a covered or non-covered health service. Benefit coverage for health services is determined by the member specific benefit plan document and applicable laws that may require coverage for a specific service. The inclusion of a code does not imply any right to reimbursement or guarantee claim payment. Other Policies and Coverage Determination Guidelines may apply.

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<td>Development of cognitive skills to improve attention, memory, problem solving (includes compensatory training), direct (one-on-one) patient contact, each 15 minutes</td>
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DESCRIPTION OF SERVICES

According to the Centers for Disease Control and Prevention (CDC), "a traumatic brain injury is caused by a bump, blow or jolt to the head or a penetrating head injury that disrupts the normal function of the brain" (2016).

Brain injury is defined as damage to the brain caused by externally inflicted trauma or damage due to stroke, aneurysm, anoxia, encephalitis, brain tumors, and brain toxins. Either type of injury may result in significant physical, cognitive, and psychosocial impairment in functioning and consciousness.

Cognitive rehabilitation targets such functions as attention, memory and learning, affect and expression, problem solving, and executive function. Two basic approaches to cognitive rehabilitation are used: (1) restorative (remedial) cognitive rehabilitation, where intellectual deficits are bolstered by various repetitive exercises; and (2) compensatory (adaptive) cognitive rehabilitation, where adaptive devices and strategies and modification of the environment are
used to restore functioning despite ongoing deficits. These 2 techniques can be used in combination and can also be components of a comprehensive rehabilitation program that involves other forms of remediation and psychosocial therapy. (Hayes, 2016).

Coma (or sensory) stimulation is proposed to promote awakening of brain-injured patients from a coma or vegetative state. This may involve stimulation of any or all of the senses with various stimuli for each sense. There is not an established protocol for completing this type of stimulation or definitive patient selection criteria.

**CLINICAL EVIDENCE**

While cognitive rehabilitation (CR) has been investigated in a wide variety of indications, the bulk of the literature has focused on traumatic brain injury (TBI) and stroke. The evidence in the published medical literature is difficult to assess due to variability in study design, low power to detect difference or variation in treatment. Variation in treatment is related to the heterogeneous nature of the treated population; specific CR interventions are typically targeted to the specific deficit. Given these limitations, the published data provides the most support for effectiveness of CR in individuals with TBI.

**Brain Injury**

In a systematic review, Cicerone et al. (2011) evaluated 112 studies to update clinical recommendations for CR in individuals with TBI and stroke. Of the 112 studies, 14 were rated as class I, 5 as class IA, 11 as class II, and 82 as class III. Evidence within each area of intervention was synthesized and recommendations for Practice Standards, Practice Guidelines, and Practice Options were made. The authors concluded that there is substantial evidence to support interventions for attention, memory, social communication skills, executive function, and for comprehensive-holistic neuropsychologic rehabilitation after TBI. Evidence supports visuospatial rehabilitation after right hemisphere stroke, and interventions for aphasia and apraxia after left hemisphere stroke. According to the authors, there is sufficient information to support evidence-based protocols and implement empirically-supported treatments for cognitive disability after TBI and stroke.

**Cochrane Reviews**

An update of a Cochrane review first published in 2000 and subsequently updated in 2007 was performed in 2016 by das Nair et al. The objective was to determine whether participants who have received CR for memory problems after a stroke had better outcomes in relation to memory function, functional ability, mood, and quality of life, than those given no treatment or a placebo control. The review included 13 trials involving 514 participants. The reviewers concluded that no significant effects of treatment were found in subjective reports in the long term or on performance on objective memory measures, mood, functional abilities, or quality of life. Benefits were reported in the short term on subjective measures of memory; however, these did not persist. In addition, no benefits were reported in objective memory measures, mood, or daily functioning. There was insufficient evidence to support or refute the effectiveness of memory rehabilitation after stroke. This may be because of poor methodological quality of the included studies, inconsistencies in the choice of outcome measures, and small sample sizes. Furthermore, more robust trials of memory rehabilitation that use standardized activity or participatory level outcome measures are required.

In other Cochrane reviews, analyses by Loetscher and Lincoln (2013) and Bowen et al. (2013) concluded that the long term effectiveness of CR remains unconfirmed after examining studies involving 223 and 628 participants respectively. The reviewers concur that further high quality clinical trials are required.

**Position and Practice Statements**

Guidance from the National Institute for Health and Care Excellence (NICE) on stroke rehabilitation recommends CR with interventions for memory and cognitive functions that focus on the relevant functional tasks, taking into account the underlying impairment. Interventions could include increasing awareness of the memory deficit, enhancing learning using errorless learning and elaborate techniques (making associations, use of mnemonics, internal strategies related to encoding information such as 'preview, question, read, state, test'), external aids (for example, diaries, lists, calendars and alarms), or environmental strategies (routines and environmental prompts (2013)).

The Institute of Medicine released a report on Cognitive Rehabilitation Therapy (CRT) for TBI at the request of the U.S. Department of Defense. The report, which reviewed 90 studies published from 1991 to 2011, states that current evidence provides limited support for the efficacy of CRT for TBI. The report states that there is some evidence about the potential value of CRT for treating TBI, but overall it is not sufficient to develop definitive guidelines on how to apply these therapies and to determine which type of CRT will work best for a particular patient. Despite the methodological shortcomings of the evidence, the authors of the report support the ongoing clinical application of CRT interventions for individuals with cognitive and behavioral deficits due to TBI (2011).

The Agency for Healthcare Research and Quality (AHRQ) issued a comparative effectiveness review on multidisciplinary CR for moderate to severe TBI in adults. The goal of the review was to identify the most effective
multidisciplinary postacute rehabilitation interventions for this demographic. The report evaluated 16 studies assessing prespecified primary outcomes or secondary patient-centered outcomes. The authors concluded that the body of evidence is not informative regarding effectiveness or comparative effectiveness of multidisciplinary postacute rehabilitation, stating that failure to draw broad conclusions must not be misunderstood to be evidence of ineffectiveness. According to the authors, the limited evidence on this topic stems from the complexity of the condition and treatments resulting in limited available research and from limitations within that research to answer salient research questions about what works for which patients. Further research should address methodological flaws common in these studies as well as questions regarding efficacy (Brasure et al. 2012; updated 2016).

**Schizophrenia**

A systematic review by Isaac and Januel assessed the effect of cognitive remediation programs on neural processes. 15 reports included 19 randomized controlled studies on 455 adult patients suffering from a schizophrenia spectrum disorder. Overall, the reviewers concluded that studies provided interesting conclusions on a possible neuroplastic effect of cognitive remediation in schizophrenia through functional reorganization of neural networks, superior to other interventions or usual care. Specifically, cognitive remediation can improve various cortical and subcortical activations, including frontal activation associated with high-level cognitive and social-cognitive functions. Further randomized controlled studies are needed to confirm or clarify existing results, in order to provide stronger evidence for a neurobiological effect of cognitive remediation programs in schizophrenia spectrum disorders (2016).

Barlati et al. (2012) reviewed the available literature on cognitive remediation in the early course of schizophrenia. According to the authors, few studies on the effects of cognitive training programs have been conducted in first episode or in early schizophrenia and only one study has been conducted in the prodromal phase (period of decreased functioning that may correlate with the onset of psychotic symptoms of the disease). The authors state that although preliminary positive results have been achieved, more research is needed to confirm the efficacy of cognitive remediation in the early course of schizophrenia.

A randomized controlled trial by Eack et al. (2010) compare CR (n=31) with supportive therapy (n=27) in patients with either early schizophrenia (n=35) or schizoaffective disorder (n=18). All patients were stable on anti-psychotic medication. The CR group received 60 hours of weekly computer-based neurocognitive training coupled with 45 weekly social-cognitive group sessions. The supportive therapy group only received individual psychotherapy. Fifty-three patients (30 CR and 23 supportive therapy subjects) underwent MRI to evaluate gray matter in the brain. The supportive therapy group showed greater loss of gray matter on MRI compared to the CR group. The authors found that the CR group had a decrease in loss of, and, in some cases, an increase in gray matter compared with the supportive therapy group. The area with less loss was related to improved neurocognitive function. The authors concluded that CR can protect against gray matter loss and may therefore decrease cognitive impact in this group of patients. Further studies must compare CR to a treatment of known and predictable effectiveness, e.g., pharmacotherapy with anti-psychotic agents.

**Other Disorders**

CR has also been investigated for disorders such as cerebral palsy, Down syndrome, Alzheimer's disease, attention deficit hyperactivity disorder, developmental disorders such as autism, and Parkinson's disease. There is little evidence that CR is beneficial for these conditions.

In 2013, Reichow et al. reported a systematic review of psychosocial interventions administered by nonspecialists for children and adolescents with intellectual disability or lower-functioning autism-spectrum disorders. Five comparative trials in patients with autism-spectrum disorders (total N=255) who received CR, training, and support were included. Improvements in school performance and developmental outcomes were inconsistent across trials.

A Cochrane Review evaluated the effectiveness of cognitive training and CR for mild to moderate Alzheimer's disease (AD) and vascular dementia. The evidence reviewed included 11 trials of cognitive training and a single trial of CR. The authors found no evidence for the efficacy of cognitive training to improve cognitive functioning, mood or activities of daily living in individuals with mild to moderate AD or vascular dementia. The single trial of CR provided preliminary indications of the potential benefits of individual CR to improve activities of daily living in individuals with mild AD. The authors recommend that more high-quality trials of both cognitive training and CR are needed in order to establish the efficacy of cognitive training and CR for individuals with early-stage dementia (Bahar-Fuchs, 2013).

Kurz, et al. (2011) conducted a multicenter, randomized, controlled trial on 201 patients with mild dementia in Alzheimer's disease. The intervention comprised 12 individual weekly sessions of CR and combined 4 established strategies adopted from neurorehabilitation and psychotherapy. Activities of daily living were chosen as the primary outcome. The results showed no effect of the intervention on everyday functioning. There were improvements favoring the intervention on quality of life and treatment satisfaction and a significant antidepressant effect in female participants. The findings of this study may be helpful for designing further studies that are needed to determine the potential of CR in older adults with dementia.
Wade et al. (2003) evaluated whether a program of multidisciplinary rehabilitation and group support achieves sustained benefit for people with Parkinson’s disease. The study was a randomized controlled crossover trial comparing 144 patients and caregivers who had received rehabilitation four months before assessment with those who had not. Analysis comparing patients, before and six months after treatment showed worsening in disability, quality of life, and caregiver strain. The investigators concluded that patients with Parkinson’s disease decline significantly over six months, but a short spell of multidisciplinary rehabilitation may improve mobility.

Sonuga-Barke et al. (2013) conducted a meta-analysis of the efficacy attention deficit hyperactivity disorder (ADHD) treatments that included cognitive training. The authors concluded that better evidence for efficacy from blinded assessments is required for behavioral interventions and cognitive training before they can be supported as treatments for core ADHD symptoms.

Riccio and French (2004) evaluated available empirical support regarding the efficacy of treatments for treatment of attention deficits across disorders and age levels. The search of the major databases yielded 83 studies that included treatment of attentional deficits. A review of the studies indicated that, regardless of the treatment program or population, the existing research does not provide sufficient evidence to reach any conclusions about the efficacy of programs designed to address attention deficits. Before any conclusions can be drawn, there is a need for more rigorous study of available treatment programs across age levels and disorders, with sufficient baseline and outcome data as well as control or alternative treatment conditions.

Comatose Patients

A Cochrane systematic review was completed evaluating sensory stimulation of brain-injured patients in coma or vegetative state. This study included randomized and nonrandomized controlled trials. Three studies were identified with 68 patients in total. The overall methodological quality was poor and studies differed widely in terms of outcomes measures, study design and conduct. The conclusion was that no reliable evidence to support, or rule out, the effectiveness of multisensory programs in patients in coma or vegetative state. (Lombardi, 2002).

Professional Societies

American Academy of Neurology (AAN)

In their “Practice Parameters: Assessment and Management of Patients in the Persistent Vegetative State,” the AAN makes no reference to sensory stimulation as a treatment modality (AAN, Updated July 2016).

U.S. FOOD AND DRUG ADMINISTRATION (FDA)

Cognitive rehabilitation is not subject to U.S. Food and Drug Administration (FDA) regulation.

CENTERS FOR MEDICARE AND MEDICAID SERVICES (CMS)

Medicare does not have a National Coverage Determination (NCD) for cognitive rehabilitation. Local Coverage Determinations (LCDs) do exist which address the development of cognitive skills. Refer to the following LCDs at http://www.cms.gov/medicare-coverage-database/overview-and-quick-search.aspx:

- Home Health – Occupational Therapy
- Home Health Speech-Language Pathology
- Medicine: Occupational Therapy – Outpatient
- Medicine: Physical Therapy – Outpatient
- Medicine: Speech Language Pathology – Outpatient
- Outpatient Occupational Therapy
- Outpatient Physical and Occupational Therapy Services
- Outpatient Rehab Therapy Services billed to Medicare Part B
- Outpatient Speech Language Pathology
- Physical Medicine and Rehab Policy
- Physical Medicine and Rehabilitation Services, Physical Therapy and Occupational Therapy
- Speech Language Pathology
- Speech Language Pathology (SLP) Services: Communication Disorders
- Therapy and Rehabilitation Services
- Therapy Services (PT, OT, SLP)


REFERENCES


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