



# Louisiana

## Cognitive Rehabilitation

**Policy #** 00578

**Original Effective Date:** 10/01/2021

**Current Effective Date:** 08/12/2024

*Applies to all products administered or underwritten by Blue Cross and Blue Shield of Louisiana and its subsidiary, HMO Louisiana, Inc. (collectively referred to as the "Company"), unless otherwise provided in the applicable contract. Medical technology is constantly evolving, and we reserve the right to review and update Medical Policy periodically.*

### When Services May Be Eligible for Coverage

*Coverage for eligible medical treatments or procedures, drugs, devices or biological products may be provided only if:*

- *Benefits are available in the member's contract/certificate, and*
- *Medical necessity criteria and guidelines are met.*

Based on review of available data, the Company may consider cognitive rehabilitation (as a distinct and definable component of the rehabilitation process) for individuals with cognitive impairment due to traumatic brain injury (TBI) or stroke (ischemic or hemorrhagic) to be **eligible for coverage.\*\***

#### Patient Selection Criteria

Coverage eligibility will be considered when all of the following criteria are met:

- Documented cognitive impairment with related functional deficit; and
- Individual is willing and able to actively participate in a cognitive rehabilitation program (e.g. is not in a vegetative or comatose state); and
- There is significant potential for improvement (goals and expected timeframes should be documented prior to the onset of treatment); and
- For continuation requests, documentation supports continued need for cognitive rehabilitation based on active participation and objective progress toward quantifiable short- and long-term goals; and
- Provided by a licensed healthcare professional (e.g. neuropsychologist, psychiatrist, physician, psychologist, speech/ language therapist, physical or occupational therapist).

### When Services Are Considered Investigational

*Coverage is not available for investigational medical treatments or procedures, drugs, devices or biological products.*

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Based on review of available data, the Company considers cognitive rehabilitation (as a distinct and definable component of the rehabilitation process) for all other applications, including, but not limited to, post-concussion syndrome, attention deficit disorder, postencephalitic or post encephalopathy individuals, autism spectrum disorder, seizure disorders, multiple sclerosis, the aging population, including individuals with Alzheimer disease, individuals with cognitive deficits due to brain tumor or previous treatment for cancer, and individuals with post-acute cognitive sequelae of SARS-CoV-2 infection to be **investigational**.\*

The use of cognitive rehabilitation when patient selection criteria are not met is considered to be **investigational**.\*

## **Policy Guidelines**

For services to be considered medically necessary, they must be provided by a qualified licensed professional and must be prescribed by the attending physician as part of the written care plan. Additionally, there must be a potential for improvement (based on preinjury function), and patients must be able to participate actively in the program. Active participation requires sufficient cognitive function to understand and participate in the program, as well as adequate language expression and comprehension (ie, participants should not have severe aphasia). Ongoing services are considered necessary only when there is demonstrated continued objective improvement in function.

Duration and intensity of cognitive rehabilitation therapy programs vary. One approach for comprehensive cognitive rehabilitation is a 16-week outpatient program comprising 5 hours of therapy daily for 4 days each week. In another approach, cognitive group treatment occurs for three 2-hour sessions weekly and three 1-hour individual sessions (total, 9 hours weekly). Cognitive rehabilitation programs for specific deficits (eg, memory training) are less intensive and generally have 1 or 2 sessions (30 or 60 minutes) in a week for 4 to 10 weeks.

## **Background/Overview**

Cognitive rehabilitation is a structured set of therapeutic activities designed to retrain an individual's ability to think, use judgment, and make decisions. The focus is on improving deficits in memory, attention, perception, learning, planning, and judgment. The term *cognitive rehabilitation* is applied to various intervention strategies or techniques that attempt to help patients reduce, manage, or cope with cognitive deficits caused by brain injury. The desired outcomes are improved quality of life and

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function in home and community life. The term *rehabilitation* broadly encompasses reentry into familial, social, educational, and working environments, the reduction of dependence on assistive devices or services, and general enrichment of quality of life. Patients recuperating from traumatic brain injury have traditionally been treated with some combination of physical therapy, occupational therapy, and psychological services as indicated. Cognitive rehabilitation is considered a separate service from other rehabilitative therapies, with its own specific procedures.

## **FDA or Other Governmental Regulatory Approval**

### **U.S. Food and Drug Administration (FDA)**

Cognitive rehabilitation is not subject to regulation by the U.S. Food and Drug Administration.

## **Rationale/Source**

This medical policy was developed through consideration of peer-reviewed medical literature generally recognized by the relevant medical community, U.S. Food and Drug Administration approval status, nationally accepted standards of medical practice and accepted standards of medical practice in this community, technology evaluation centers, reference to federal regulations, other plan medical policies, and accredited national guidelines.

Cognitive rehabilitation is a therapeutic approach designed to improve cognitive functioning after central nervous system insult. It includes an assembly of therapy methods that retrain or alleviate problems caused by deficits in attention, visual processing, language, memory, reasoning, problem-solving, and executive functions. Cognitive rehabilitation comprises tasks to reinforce or reestablish previously learned patterns of behavior or to establish new compensatory mechanisms for impaired neurologic systems. Cognitive rehabilitation may be performed by a physician, psychologist, or a physical, occupational, or speech therapist.

## **Summary of Evidence**

For individuals who have cognitive deficits due to TBI who receive cognitive rehabilitation delivered by a qualified professional, the evidence includes RCTs, nonrandomized comparison studies, case series, and systematic reviews. Relevant outcomes are functional outcomes and quality of life. The cognitive rehabilitation trials have methodologic limitations and have reported mixed results, indicating there is no uniform or consistent evidence base supporting the efficacy of this technique. Systematic reviews have generally concluded that efficacy of cognitive rehabilitation is uncertain.

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The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

For individuals who have cognitive deficits due to dementia who receive cognitive rehabilitation delivered by a qualified professional, the evidence includes RCTs, nonrandomized comparison studies, case series, and systematic reviews. Relevant outcomes are functional outcomes and quality of life. A Cochrane systematic review focusing on outcomes related to everyday function found statistically significantly improved participant self-ratings of goal attainment related to everyday functioning both immediately following rehabilitation and after 3 to 12 months follow-up post-rehabilitation. There was less certainty regarding whether cognitive rehabilitation had a meaningful effect on quality of life. One large RCT evaluating a goal-oriented cognitive rehabilitation program reported a significantly less functional decline in 1 of 2 functional scales and lower rates of institutionalization in the cognitive rehabilitation group compared with usual care at 24 months. These results need replication. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

For individuals who have cognitive deficits due to stroke who receive cognitive rehabilitation delivered by a qualified professional, the evidence includes RCTs and systematic reviews. Relevant outcomes are functional outcomes and quality of life. Four systematic reviews evaluating 3 separate domains of cognitive function have shown no benefit of cognitive rehabilitation or effects of clinical importance. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

For individuals who have cognitive deficits due to MS who receive cognitive rehabilitation delivered by a qualified professional, the evidence includes RCTs and systematic reviews. Relevant outcomes are functional outcomes and quality of life. Systematic reviews of RCTs have shown no significant effects of cognitive rehabilitation on cognitive outcomes. Although numerous RCTs have investigated cognitive rehabilitation for MS, high-quality trials are lacking. The ability to draw conclusions based on the overall body of evidence is limited by the heterogeneity of patient samples, interventions, and outcome measures. Further, results of the available RCTs have been mixed, with positive studies mostly reporting short-term benefits. Evidence for clinically significant, durable improvements in cognition is currently lacking. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

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For individuals who have cognitive deficits due to post-acute sequelae of SARS-CoV-2 infection who receive cognitive rehabilitation delivered by a qualified professional, no relevant evidence was identified. Relevant outcomes are functional outcomes and quality of life. Systematic reviews have reported on the prevalence and duration of cognitive symptoms among patients with varying acute infection severity and treatment settings. Limited reports examining the outcomes of rehabilitation in patients with post-acute COVID-19 have primarily focused on physical and respiratory rehabilitation. Additionally, the natural history of cognitive deficits experienced by patients who have recovered from acute COVID-19 requires further elucidation. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

For individuals who have cognitive deficits due to epilepsy, ASD, post encephalopathy, or cancer who receive cognitive rehabilitation delivered by a qualified professional, the evidence includes RCTs, nonrandomized comparison studies, and case series. Relevant outcomes are functional outcomes and quality of life. The quantity of studies for these conditions is much less than that for the other cognitive rehabilitation indications. Systematic reviews generally have not supported the efficacy of cognitive rehabilitation for these conditions. Relevant RCTs have had methodologic limitations, most often very short lengths of follow-up, which do not permit strong conclusions about efficacy. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

### **Additional Information**

Clinical input obtained in 2010 provided the strongest support for the use of cognitive rehabilitation as part of the treatment of traumatic brain injuries. As part of clinical input obtained in 2015, the American Association of Physical Medicine & Rehabilitation reasserted its position of support. Cognitive rehabilitation may be considered medically necessary for traumatic brain injury based on this input.

## **Supplemental Information**

### **Clinical Input From Physician Specialty Societies and Academic Medical Centers**

While the various physician specialty societies and academic medical centers may collaborate with and make recommendations during this process, through the provision of appropriate reviewers, input received does not represent an endorsement or position statement by the physician specialty societies or academic medical centers, unless otherwise noted.

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### 2015 Input

In response to requests, input was received from 3 physician specialty societies and 5 academic medical centers while this policy was under review in 2015. Input was mixed on cognitive rehabilitation for patients with stroke, multiple sclerosis, brain tumors, or cognitive impairments after previous treatments for cancer. While input was not specifically requested for TBI, due to strong support provided in 2009 and no signals of any subsequent evidence or clinical practice changes, the American Association of Physical Medicine & Rehabilitation voluntarily and additionally reasserted its position of support for cognitive rehabilitation after TBI.

### 2009/2010 Input

In response to requests, input was received from 2 physician specialty societies and 5 academic medical centers while this policy was under review in 2010. The strongest support was for the use of cognitive rehabilitation as part of the treatment of those with TBI. The level of support varied for other diagnoses (eg, use in post-stroke patients).

### Practice Guidelines and Position Statements

Guidelines or position statements will be considered for inclusion in 'Supplemental Information' if they were issued by, or jointly by, a US professional society, an international society with US representation, or National Institute for Health and Care Excellence (NICE). Priority will be given to guidelines that are informed by a systematic review, include strength of evidence ratings, and include a description of management of conflict of interest.

### American Academy of Physical Medicine and Rehabilitation

In 2021, the American Academy of Physical Medicine and Rehabilitation (AAPM&R) Multi-Disciplinary Post-Acute Sequelae of SARS-CoV-2 Infection (PASC) Collaborative issued a consensus guidance statement on the assessment and treatment of cognitive symptoms in patients with PASC. PASC cognitive symptom assessment and treatment recommendations are summarized in Table 1.

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**Table 1. Post-Acute Sequelae of SARS-CoV-2 Infection Cognitive Symptom Assessment and Treatment Recommendations<sup>a</sup>**

Assessment Recommendations	
Recommendation #	Statement
1	"Patients should be screened for signs of cognitive symptoms using validated tools and instruments."
2	<p>"Patients should be evaluated for conditions that may exacerbate cognitive symptoms and warrant further testing and potential subspecialty referral. [...] Particular areas include:</p> <ul style="list-style-type: none"><li>• Sleep impairment</li><li>• Mood, including anxiety, depression, and posttraumatic stress disorder</li><li>• Fatigue</li><li>• Endocrine abnormalities</li><li>• Autoimmune disorders</li></ul> <p>Note: Patients often report dissatisfaction with their care because of their persistent symptoms being attributed to psychological factors. It is important to note that mood disorders may be secondary to persistent medical conditions or one of many factors leading to cognitive symptoms."</p>
3	"Patients should have a thorough neurological examination to identify focal neurological deficits."
3a	"For those patients identified with new or worsening focal neurological deficits (including new or worsening cognitive symptoms) an emergent evaluation is warranted; neuroimaging should be considered."
4	"The following basic lab workup should be considered to screen for reversible factors contributing to cognitive symptoms. The initial lab workup in new patients or those without lab workup in the 3 months prior

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	to visit including complete blood count, vitamin B12, thiamine, folate, homocysteine, 1,25-dihydroxy vitamin D, magnesium, liver function tests, comprehensive metabolic panel thyroid function tests (thyroid stimulating hormone, free T3, free T4). In high-risk patients, one may consider syphilis rapid plasma regain and human immunodeficiency virus testing [...]"
<b>5</b>	"Clinicians should conduct a full patient history with review of preexisting conditions and comprehensive medication and supplement review for those that may contribute to cognitive symptoms.  Of note, patients with PASC often present on antihistamine, anticholinergic, and antidepressant/anxiolytic medications that can contribute to cognitive symptoms."
<b>5a</b>	"Clinicians should validate patient history through the collection of collateral history, including preexisting function and conditions, from care team/primary care, patient family or care partner, or close contact as available."
<b>6</b>	"Clinicians should assess impact of cognitive symptoms using standardized patient-reported assessments, to include activities of daily living, instrumental activities of daily living, school, work and avocational (ie, hobbies), and quality of life."
<b>Treatment Recommendations</b>	
<b>Recommendation #</b>	<b>Statement</b>
<b>1</b>	"For patients who screen positive for cognitive symptoms, refer to a specialist (ie, speech-language pathologist, occupational therapist, neuropsychologist) with expertise in formal cognitive assessment and remediation."
<b>2</b>	"Treat, in collaboration with appropriate specialists, underlying medical conditions, such as pain, insomnia/sleep disorders (including poor sleep

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	hygiene), and mood disorders that may be contributing to cognitive symptoms."
<b>3</b>	"Complete, in collaboration with patient primary care provider, medication polypharmacy reduction, weaning or deprescribing medications if medically feasible with emphasis on medications that may impact cognition."
<b>4</b>	"Reinforce sleep hygiene techniques including nonpharmacologic approaches as first line of sleep remediation."
<b>5</b>	"Similar to patients experiencing “physical” fatigue, patients should be advised to begin an individualized and structured, titrated return to activity program."
<b>5a</b>	"For patients who achieve a return to their normal, daily activities, regular exercise (at least 2–3 times/week of aerobic exercise) may be effective in improving cognition and also contribute to improved sleep patterns."
<b>5b</b>	"Frequent assessment of the impact of return to normal, daily activities (including school, work, driving, operating heavy machinery, etc.) is recommended to ensure that symptoms do not flare and exercise is tolerated."

<sup>a</sup> Adapted from Fine et al (2021).

In 2023, the American Academy of Physical Medicine and Rehabilitation (AAPM&R) Multi-Disciplinary Post-Acute Sequelae of SARS-CoV-2 Infection (PASC) Collaborative issued a consensus guidance statement on the assessment and treatment of neurologic symptoms in patients with PASC. PASC neurologic symptom assessment and treatment recommendations are summarized in Table 2.

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**Table 2. Post-Acute Sequelae of SARS-CoV-2 Infection Neurologic Symptom Assessment and Treatment Recommendations<sup>a</sup>**

Assessment Recommendations	
Recommendation #	Statement
1	"Clinicians should conduct a full patient history including a review of predisposing comorbidities, prior neurologic symptoms or disorders, relevant hospitalizations, time course and severity of COVID-19 infection(s), COVID-19 treatments, vaccines/boosters, pertinent family history, and social history."
2	"Clinicians should perform a thorough neurological examination to identify focal neurological deficits."
3	"Evaluate for medication and supplement use that may impact signs, symptoms, or assessment parameters"
4	"The following basic lab workup should be considered in new patients or for those without a lab workup in the 3 months prior to the visit: complete blood count with differential; chemistries including renal and hepatic function tests, thyroid stimulating hormone, c-reactive protein, erythrocyte sedimentation rate, vitamins B1, B6, B12, and D, magnesium, and hemoglobin A1c (HbA1c)."
5	"Assess for history of previous and/or current alcohol and substance use, current diet and exercise habits, physical and cognitive activity levels, and social determinants of health (eg, housing, employment, family, insurance, access to community resources, social stressors, etc.)"
6	"Assess for changes in basic and instrumental activities of daily living, including participation at work, school, community avocational (ie, hobbies) activities."
7	"On initial evaluation, obtain standardized measures of activity performance to compare to normal control values and to guide the initial



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	activity prescription. Repeat the standardized measures of activity performance at follow-up visits to quantify functional changes and guide progression of the activity prescription."
<b>Treatment Recommendations</b>	
<b>Recommendation #</b>	<b>Statement</b>
<b>1</b>	"In collaboration with primary care or appropriate specialist treat underlying medical conditions, such as pain, psychiatric, renal/endocrine, cardiovascular, neurological, respiratory, etc., which may be contributing to neurologic symptoms."
<b>2</b>	"In collaboration with primary care or appropriate specialist, consider polypharmacy reduction, weaning or deprescribing medications and supplements where medically feasible."
<b>3</b>	"For patients who achieve a return to their daily activities, consider recommending regular physical activity as tolerated, which may be effective in improving many neurologic symptoms and also contribute to improved sleep patterns."
<b>4</b>	"For patients with neurologic sequelae affecting gait, mobility, cognitive status or activities of daily living, consider referral to physical medicine and rehabilitation physician and/or allied health professionals (eg, physical therapy, occupational therapy, speech language pathology and social work) for patient-specific recommendations to increase function and independence. To optimize functional outcomes, allied health professionals should preferably be familiar with treating sensorimotor deficits, autonomic dysfunction, and post-exertional fatigue."
<b>5</b>	"Provide counseling, referrals to community resources, and education for risk factor modification in the areas of: alcohol and substance use; healthy dietary pattern and hydration; return to activity, as tolerated; medications and supplements; sleep hygiene; social determinants of health."

<sup>a</sup> Adapted from Melamed et al (2023).

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### **American Congress of Rehabilitation Medicine**

In 2013, based on a systematic review, the American Congress of Rehabilitation Medicine recommended process-based cognitive rehabilitation strategies (eg, attention process training, strategy acquisition and internalization, self-monitoring, corrective feedback) to treat attention and memory deficits in children and adolescents with brain cancers who undergo surgical resection and/or radiotherapy. The strength of evidence for recommendations were determined according to American Academy of Neurology study classification, and no financial conflicts of interest were declared by the authors.

### **National Institute for Health and Care Excellence**

In 2013 (updated in 2023), NICE guidance on stroke rehabilitation recommended cognitive rehabilitation for visual neglect and memory and attention deficits that impact function. Interventions should focus on relevant functional tasks (eg, "errorless learning") and "elaborative techniques" (eg, "mnemonics," "encoding" strategies) for memory impairments. The guidance states that providers should 'Make special arrangements for people after stroke who have communication or cognitive needs (for example, by holding joint speech and language therapy and physiotherapy sessions for those with communication difficulties).'

In 2018, NICE guidance on dementia management suggested: "Consider cognitive rehabilitation or occupational therapy to support functional ability in people living with mild to moderate dementia."

In 2021 (updated in 2024), NICE issued a rapid guideline on managing the long-term effects of COVID-19. The guideline recommends using a "multidisciplinary approach to guide rehabilitation, including physical, psychological and psychiatric aspects of management." Cognitive rehabilitation was not specifically addressed. Assessing the clinical effectiveness of "different service models of multimodality/multidisciplinary post-COVID-19 syndrome rehabilitation in improving patient-reported outcomes (such as quality of life)" was listed as a key recommendation for research.

The NICE guidance development is a transparent process that provides detailed information on the strength of recommendations and information on potential conflicts of interest for guideline committee members.

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### **Institute of Medicine**

In 2011, the Institute of Medicine published a report on cognitive rehabilitation for traumatic brain injury that included a comprehensive review of the literature and recommendations. The report concluded that "current evidence provides limited support for the efficacy of CRT [cognitive rehabilitation therapy] interventions. The evidence varies in both the quality and volume of studies and therefore is not yet sufficient to develop definitive guidelines for health professionals on how to apply CRT in practice." The report recommended that standardization of clinical variables, intervention components, and outcome measures was necessary to improve the evidence base for this treatment. The Institute of Medicine also recommended future studies with larger sample sizes and more comprehensive sets of clinical variables and outcome measures.

### **Veterans Administration**

In 2009, the Veterans Administration/Department of Veterans Affairs published guidelines on the treatment of concussion and mild traumatic brain injury, which were updated in 2016 and most recently in 2021. These guidelines addressed cognitive rehabilitation in the setting of persistent symptoms. The 2021 guidelines stated:

- "We suggest that patients with symptoms attributed to mild traumatic brain injury [mTBI] who present with memory, attention, or executive function problems despite appropriate management of other contributing factors (e.g., sleep, pain, behavioral health, headache, disequilibrium) should be referred for a short trial of clinician-directed cognitive rehabilitation services." [Strength of recommendation: "weak for."]
- "We suggest against the use of self-administered computer training programs for the cognitive rehabilitation of patients with symptoms attributed to mTBI." [Strength of recommendation: "weak against."]

A 2019 Veterans Administration/Department of Defense practice guideline on the management of stroke rehabilitation found "insufficient evidence to recommend for or against the use of any specific cognitive rehabilitation methodology or pharmacotherapy to improve cognitive outcomes" and noted "there has been very little advancement in the evidence regarding the use of specific cognitive rehabilitation strategies or techniques to improve clinical outcomes following stroke."

### **U.S. Preventive Services Task Force Recommendations**

Not applicable.

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Medicare National Coverage

There is no national coverage determination. In the absence of a national coverage determination, coverage decisions are left to the discretion of local Medicare carriers.

Ongoing and Unpublished Clinical Trials

Some currently unpublished trials that might influence this review are listed in Table 3.

Table 3. Summary of Key Trials

NCT No.	Trial Name	Planned Enrollment	Completion Date
<i>Ongoing</i>			
NCT01138020	Cognitive Rehabilitation of Blast-induced Traumatic Brain Injury (CRbTBI)	77	Oct 2026
NCT03900806	Internet-based Work-related Cognitive Rehabilitation for Cancer Survivors: a Randomized Controlled Trial (i-WORC)	261	Aug 2023
NCT04615390	Recovery Profiles in Patients With COVID-19 Outcomes Undergoing Rehabilitation	200	Nov 2023
NCT03168360	Effect of Intensive Cognitive Rehabilitation in Subacute Stroke Patient	150	Dec 2023
NCT04632719	MentalPlus <sup>®†</sup> for Assessment and Rehabilitation of Cognitive Functions After Remission of Symptoms of COVID-19 (MP-COVID)	200	Dec 2023
NCT05172206	Symptom-based Rehabilitation Compared to Usual Care in Post-COVID - a Randomized Controlled Trial (RELOAD)	132	Dec 2023
NCT05731570	Cognitive Impairment in Long Covid: Phenotyping and Rehabilitation (CICERO)	120	Feb 2024





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NCT03225482	Cognitive Rehabilitation for Older Veterans With Mild Cognitive Impairment	216	Mar 2024
NCT04229056	Computer-Assisted Self-Training to Improve Executive Function Versus Unspecific Training in Patients After Stroke, Cardiac Arrest or in Parkinson's Disease: A Randomized Controlled Trial (COMPEX)	700	Dec 2024
NCT05676047	Symptom-Targeted Rehabilitation for Cognitive Complaints in Long COVID (STAR-C3)	100	Dec 2024
NCT03948490	Rehabilitation and Longitudinal Follow-up of Cognition in Adult Lower Grade Gliomas	180	Mar 2025
NCT06021470	The StrokeCog Study: a Randomised Pilot Study of a Novel Cognitive Rehabilitation Intervention in Stroke	64	Oct 2025
NCT05954741	Comparing the Effectiveness of Multidimensional Rehabilitation Programs for Cognitive Impairment in Comorbid Outpatients: a Randomized Controlled Trial	75	Jan 2026
NCT05934786	Rehabilitation of Cognition and Psychosocial Well-being - A Better Life With Epilepsy	70	Dec 2028
NCT05494424	Cognitive Rehabilitation in Post-COVID-19 Condition: A Study Protocol for a Randomized Controlled Trial	240	Jan 2029
<i>Unpublished</i>			
NCT03237676	The Effect of Cognitive Rehabilitation Therapy in Improving Cognitive Function of Attention Following Mild Traumatic Brain Injury	90	Dec 2019

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NCT04852718	Evaluate a Rehabilitation Program for the Sequelae of COVID 19 Infection: Description of a Clinical Practice	120	Apr 2021
NCT03679468	Improving Cognition in People With Progressive Multiple Sclerosis: A Multi-Arm, Randomized, Blinded, Sham-Controlled Trial of Cognitive Rehabilitation and Aerobic Exercise.	309	Feb 2023

NCT: national clinical trial.

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## **Policy History**

Original Effective Date: 10/01/2021

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07/01/2021 Medical Policy Committee review

07/14/2021 Medical Policy Implementation Committee approval. New policy.

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07/07/2022 Medical Policy Committee review  
07/13/2022 Medical Policy Implementation Committee approval. Investigational policy statement for post-acute cognitive sequelae of SARS-CoV-2 infection was added.  
07/06/2023 Medical Policy Committee review  
07/12/2023 Medical Policy Implementation Committee approval. No change to coverage.  
07/02/2024 Medical Policy Committee review  
07/10/2024 Medical Policy Implementation Committee approval. No change to coverage.  
Next Scheduled Review Date: 07/2025

## Coding

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Codes used to identify services associated with this policy may include (but may not be limited to) the following:

Code Type	Code
CPT	97129, 97130
HCPCS	No codes
ICD-10 Diagnosis	F01.50-F01.C4, F02.80-F02.C4, F03.90-F03.C4, F07.81, F44.5, F84.0-F84.9, F90.0-F90.9, G30.0-G30.9, G31.0-G31.9, G35, G40.0-G40.919, G45.0-G45.9, G46.0-G46.8, G93.40-G93.49, R56.1, S06.0-S06.9X9, S06.A0XA-S06.A1XS

**\*Investigational** – A medical treatment, procedure, drug, device, or biological product is Investigational if the effectiveness has not been clearly tested and it has not been incorporated into standard medical practice. Any determination we make that a medical treatment, procedure, drug, device, or biological product is Investigational will be based on a consideration of the following:

- A. Whether the medical treatment, procedure, drug, device, or biological product can be lawfully marketed without approval of the U.S. Food and Drug Administration (FDA) and whether such approval has been granted at the time the medical treatment, procedure, drug, device, or biological product is sought to be furnished; or
- B. Whether the medical treatment, procedure, drug, device, or biological product requires further studies or clinical trials to determine its maximum tolerated dose, toxicity, safety, effectiveness, or effectiveness as compared with the standard means of treatment or diagnosis, must improve health outcomes, according to the consensus of opinion among experts as shown by reliable evidence, including:
  1. Consultation with technology evaluation center(s);
  2. Credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community; or
  3. Reference to federal regulations.

**\*\*Medically Necessary (or “Medical Necessity”)** - Health care services, treatment, procedures, equipment, drugs, devices, items or supplies that a Provider, exercising prudent clinical judgment, would provide to a patient for the purpose of preventing, evaluating, diagnosing or treating an illness, injury, disease or its symptoms, and that are:

- A. In accordance with nationally accepted standards of medical practice;

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- B. Clinically appropriate, in terms of type, frequency, extent, level of care, site and duration, and considered effective for the patient's illness, injury or disease; and
- C. Not primarily for the personal comfort or convenience of the patient, physician or other health care provider, and not more costly than an alternative service or sequence of services at least as likely to produce equivalent therapeutic or diagnostic results as to the diagnosis or treatment of that patient's illness, injury or disease.

For these purposes, “nationally accepted standards of medical practice” means standards that are based on credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community, Physician Specialty Society recommendations and the views of Physicians practicing in relevant clinical areas and any other relevant factors.

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**NOTICE:** Federal and State law, as well as contract language, including definitions and specific contract provisions/exclusions, take precedence over Medical Policy and must be considered first in determining eligibility for coverage.

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