



MEDICAL COVERAGE POLICY

SERVICE: Digital Cognitive Behavioral Therapy

Policy Number: 302

Effective Date: 05/01/2024

Last Review: 04/08/2024

Next Review: 04/08/2025

Important note: Unless otherwise indicated, medical policies will apply to all lines of business. Medical necessity as defined by this policy does not ensure the benefit is covered. This medical policy does not replace existing federal or state rules and regulations for the applicable service or supply. In the absence of a controlling federal or state coverage mandate, benefits are ultimately determined by the terms of the applicable benefit plan documents. See the member plan specific benefit plan document for a complete description of plan benefits, exclusions, limitations, and conditions of coverage. In the event of a discrepancy, the plan document always supersedes the information in this policy.

SERVICE: Digital Cognitive or Behavioral Therapy

PRIOR AUTHORIZATION: Required.

POLICY: Please review the plan’s EOC (Evidence of Coverage) or Summary Plan Description (SPD) for details. Not all plans cover this therapy.

This policy addresses the use of practitioner-prescribed software applications for health management purposes for use on a mobile device (e.g., mobile phone, laptop, smartwatch, or tablet) with the intent to evaluate, diagnose or treat a medical condition. This policy does NOT address mobile-based software applications that are used in the management of another FDA-cleared or approved stand-alone hardware medical device. In addition, this policy does not address mobile-based software applications available to the general public for download (including direct-to-consumer or “over the counter” applications), applications that promote general wellness, or applications operated by a healthcare practitioner in a clinical setting for remote health monitoring.

Note: Unless otherwise indicated (see below), this policy will apply to all lines of business.

For Medicare plans, please refer to appropriate Medicare NCD (National Coverage Determination) or LCD (Local Coverage Determination). Medicare NCD or LCD specific InterQual criteria may be used when available. If there are no applicable NCD or LCD criteria, use the criteria set forth below.

For Medicaid plans, please confirm coverage as outlined in the [Texas Medicaid Provider Procedures Manual | TMHP](#) (TMPPM). If there are no applicable criteria to guide medical necessity decision making in the TMPPM, use the criteria set forth below.

BSWHP may consider digital cognitive behavioral therapy medically necessary when **ALL** of the following criteria are met:

- A. Criteria for the mobile software application (MSA) (See table below):
 1. The MSA has been approved or cleared by the Food and Drug Administration (FDA); and
 2. There is credible scientific evidence which permits reasonable conclusions regarding the impact of the MSA on health outcomes; AND
 3. The MSA has been proven materially to improve the net health outcome or be as beneficial as any established alternative



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B. Member criteria to evaluate the appropriateness of the MSA for the individual:

1. The MSA has been prescribed by a healthcare practitioner; AND
2. There is documentation supporting that the MSA was ordered for a covered purpose such as preventing, evaluating, diagnosing or treating an illness, injury, disease or its symptoms, and in accordance with generally accepted standards of medical practice; AND
3. The requested MSA is not primarily for the convenience of the individual, caregiver, or healthcare provider

The following mobile software applications have been evaluated and have medical benefit (See “A” above). All others digital therapy applications are deemed experimental, investigational, unproven, because of a paucity of well-designed, controlled, clinical trials demonstrating clinical efficacy of the intervention:

Digital Therapeutic	Intervention or Treatment	Methodology	BSW Health Plan Status
Somryst	Chronic Insomnia	Cognitive behavioral therapy 9-week Prescription Digital Therapeutic	Medically necessary if criteria met

BACKGROUND:

Digital therapy encompasses technologies, platforms, and systems that engage members for lifestyle, wellness, and other health-related purposes. These therapies use software programs to prevent, manage, or treat a medical disorder or disease. Similar to pharmaceutical agents and medical devices, digital therapies are evaluated and approved by the U.S. Food and Drug Administration (FDA).

CODES:

Important note: Due to the wide range of applicable diagnosis codes and potential changes to codes, an inclusive list may not be presented, but the following codes may apply. Inclusion of a code in this section does not guarantee that it will be reimbursed, and patient must meet the criteria set forth in the policy language.

CPT Codes	
CPT Not Covered	98978 - Remote therapeutic monitoring (eg, therapy adherence, therapy response); device(s) supply with scheduled (eg, daily) recording(s) and/or programmed alert(s) transmission to monitor cognitive behavioral therapy, each 30 days
HCPCS Codes	A9291 - Prescription digital cognitive and/or behavioral therapy, FDA-cleared, per course of treatment
HCPCS Codes Not covered	T1505 - Electronic medication compliance management device, includes all components and accessories, not otherwise classified
ICD10 codes	



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POLICY HISTORY:

Status	Date	Action
New	03/30/2023	New policy
Reviewed	04/08/2024	Formatting changes, added hyperlinks to TMPPM, beginning and ending note sections updated to align with CMS requirements and business entity changes; added references to align with current evidence.

REFERENCES:

The following scientific references were utilized in the formulation of this medical policy. BSWHP will continue to review clinical evidence related to this policy and may modify it at a later date based upon the evolution of the published clinical evidence. Should additional scientific studies become available, and they are not included in the list, please forward the reference(s) to BSWHP so the information can be reviewed by the Medical Coverage Policy Committee (MCPC) and the Quality Improvement Committee (QIC) to determine if a modification of the policy is in order.

1. Digital Health Center of Excellence. Available from FDA.
2. Food and Drug Administration. Policy for device software functions and mobile medical applications: guidance for industry and Food and Drug Administration staff.
3. International Medical Device Regulators Forum. Software as a Medical Device (SaMD): key definitions.
4. Morin CM. Profile of Somryst prescription digital therapeutic for chronic insomnia: overview of safety and efficacy. *Expert Rev Med Devices*. 2020;17(12):1239-1248. doi:10.1080/17434440.2020.1852929
5. Steven W. Evans, Theodore P. Beauchaine, Andrea Chronis-Tuscano, Stephen P. Becker, Anil Chacko, Richard Gallagher, Cynthia M. Hartung, Michael J. Kofler, Brandon K. Schultz, Leanne Tamm & Eric A. Youngstrom (2021) The Efficacy of Cognitive Videogame Training for ADHD and What FDA Clearance Means for Clinicians, *Evidence-Based Practice in Child and Adolescent Mental Health*, 6:1, 116-130, DOI: 10.1080/23794925.2020.1859960
6. Hayes Reviews. Available at <https://evidence.hayesinc.com/>. Requires subscription.

Note:

Health Maintenance Organization (HMO) products are offered through Scott and White Health Plan dba Baylor Scott & White Health Plan, and Scott & White Care Plans dba Baylor Scott & White Care Plan. Insured PPO and EPO products are offered through Baylor Scott & White Insurance Company. Scott and White Health Plan dba Baylor Scott & White Health Plan serves as a third-party administrator for self-funded employer-sponsored plans. Baylor Scott & White Care Plan and Baylor Scott & White Insurance Company are wholly owned subsidiaries of Scott and White Health Plan. These companies are referred to collectively in this document as Baylor Scott & White Health Plan.

RightCare STAR Medicaid plans are offered through Scott and White Health Plan in the Central Managed Care Service Area (MRSA) and STAR and CHIP plans are offered through SHA LLC dba FirstCare Health Plans (FirstCare) in the Lubbock and West MRSAs.