Sentara Health Plans

Medicare

Prescription Digital Therapeutics and Devices, Medical 259

Table of Content

Effective Date	4/1/2026
Next Review Date	12/2026
Coverage Policy	Medical 259
Version	9

Member-specific benefits take precedence over medical policy and benefits may vary across plans. Refer to the individual's benefit plan for details*.

Description & Definitions:

Prescription Digital Therapeutics (PDTs) are software-based treatments accessible on smartphones, tablets, Head-Mounted Displays (HMDs) and other wearable devices prescribed by a licensed healthcare practitioner, designed to assist with managing or treating medical disorders or diseases.

Computerized Behavioral Therapy Device is a software-based mobile app downloaded onto a smartphone, that provides a computerized version of behavioral therapy to the patient.

Mobile-based health management includes mobile software application (MSA) and software-based technologies created with the intention of gathering useful health information through a mobile platform.

Actigraphy is a non-invasive way to observe an individual's sleep patterns of rest/activity cycles using a small device like a wristwatch.

XXXXX Please see plan documents for benefit coverage of software/digital therapeutics. When listed as not a covered benefit, the corresponding device/hardware is as well.

Criteria:

Prescription Digital Therapeutics (PDTs), wearable devices, software and mobile applications are considered medically necessary when **1 or more of the following** criteria have been met:

- New Tech criteria to evaluate **Prescription Digital Therapeutics (PDTs) devices, software or mobile applications** and its appropriateness for the individual with ALL of the following:
  - The prescription digital therapeutic requires a prescription by a licensed healthcare practitioner; and

- The prescription digital therapeutic has been approved by the Food and Drug Administration (FDA) and used in accordance with the FDA indications
- There is documentation supporting that the prescription digital therapeutic device or application is required was ordered for a covered purpose such as preventing, evaluating, diagnosing, or treating an illness, injury or disease or its symptoms and in accordance with generally accepted standards of medical practice
- The device or application has demonstrated, through existing peer-reviewed, evidence-based, scientific literature to be safe and effective for treating the condition or sickness for which its use is proposed
- Not primarily for the convenience of the patient, physician or other health care provider
- The prescription digital therapeutic has been proven to improve the net health outcome or is considered as beneficial as another established alternative.

***Note:** Remote therapeutic monitoring is considered an integral part of prescription digital therapeutics and is not separately reimbursable.

The following Prescription Digital Therapeutics (PDTs) devices, software or mobile applications which are considered investigational and the current role remains uncertain based on review of existing evidence. Therefore, the following are considered **not medically necessary** for any clinical indication to include, but are not limited to, the following: (this list may not be all inclusive)

- Actigraphy
- Amblyopia Digital Therapy
- Canvas Dx autism diagnosis aid,
- Contraception based fertility awareness FDA approved or cleared mobile apps
- DaylightRx
- Embrace2 Watch
- Emfit Movement Monitor
- EndeavorRx
- Freespira
- Low-Intensity Therapeutic Ultrasound (LITUS) Devices
- Mahana for irritable bowel syndrome
- MamaLift Plus
- MindMotion GO (MindMaze)
- Mobile app being used to promote fertility
- Nerivio
- NightWare
- Oura Ring
- Prescription-based video games
- Regulora for irritable bowel syndrome
- Rejoyn
- RelieVRx
- ReSet
- ReSet-O
- Sami Alert
- SleepioRx
- Smartwatches
- SmartMonitor SmartWatch Inspyre
- Somyrst

Document History:

Revised Dates:

- 2025: December – Implementation date of April 1, 2026. New criteria, exceptions, devices, coding, references updated. Name Change.
- 2025: May – Implementation date of August 1, 2025. Coding updated, references updated.

- 2025: March – Archived DME 55, criteria added to this policy. Updated codes.
- 2025: February – No criteria changes. Updated policy name. Updated to new format.
- 2020: January
- 2015: February, October
- 2014: March, May, September
- 2013: September
- 2012: July
- 2010: January, December

Reviewed Dates:

- 2024: February
- 2023: February
- 2022: February
- 2021: February
- 2020: February
- 2018: March, November
- 2017: August, September
- 2016: November
- 2015: November
- 2011: August

Origination Date: January 2011

Coding:

Medically necessary with criteria:

Coding	Description
0687T	Treatment of amblyopia using an online digital program; device supply, educational set-up, and initial session
0688T	Treatment of amblyopia using an online digital program; assessment of patient performance and program data by physician or other qualified health care professional, with report, per calendar month
0704T	Remote treatment of amblyopia using an eye tracking device; device supply with initial set-up and patient education on use of equipment
0705T	Remote treatment of amblyopia using an eye tracking device; surveillance center technical support including data transmission with analysis, with a minimum of 18 training hours, each 30 days
0706T	Remote treatment of amblyopia using an eye tracking device; interpretation and report by physician or other qualified health care professional, per calendar month
A9292	Prescription digital visual therapy, software-only, FDA cleared, per course of treatment.
A9293	Fertility cycle (contraception & conception) tracking software application, FDA cleared, per month, includes accessories (e.g., thermometer)

Considered Not Medically Necessary:

Coding	Description
95803	Actigraphy testing, recording, analysis, interpretation, and report (minimum of 72 hours to 14 consecutive days of recording)
A4540	Distal transcutaneous electrical nerve stimulator, stimulates peripheral nerves of the upper arm (replaced K1023)
A9291	Prescription digital cognitive and/or behavioral therapy, FDA-cleared, per course of treatment
A9999	Miscellaneous DME supply or accessory, not otherwise specified
E0738	Upper extremity rehabilitation system providing active assistance to facilitate muscle re-education, includes microprocessor, all components and accessories (IpsiHand™ Upper Extremity Rehabilitation System)
E0739	Rehab system with interactive interface providing active assistance in rehabilitation therapy, includes all components and accessories, motors, microprocessors, sensors
E1399	Durable medical equipment, miscellaneous
E1905	Virtual reality cognitive behavioral therapy device (CBT), including pre-programmed therapy software
G0552	Supply of digital mental health treatment device and initial education and onboarding, per course of treatment that augments a behavioral therapy plan
G0553	First 20 minutes of monthly treatment management services directly related to the patient's therapeutic use of the digital mental health treatment (DMHT) device that augments a behavioral therapy plan, physician/other qualified health care professional time reviewing information related to the use of the DMHT device, including patient observations and patient specific inputs in a calendar month and requiring at least one interactive communication with the patient/caregiver during the calendar month
G0554	Each additional 20 minutes of monthly treatment management services directly related to the patient's therapeutic use of the digital mental health treatment (DMHT) device that augments a behavioral therapy plan, physician/other qualified health care professional time reviewing data generated from the DMHT device from patient observations and patient specific inputs in a calendar month and requiring at least one interactive communication with the patient/caregiver during the calendar month (add on Code)
K1004	Low frequency ultrasonic diathermy treatment device for home use
K1036	Supplies and accessories (e.g., transducer) for low frequency ultrasonic diathermy treatment device, per month

U.S. Food and Drug Administration (FDA) - approved only products only.

The preceding codes are included above for informational purposes only and may not be all inclusive. Additionally, inclusion or exclusion of a treatment, procedure, or device-code(s) does not constitute or imply member coverage or provider reimbursement.

Special Notes: *

- Coverage: See the appropriate benefit document for specific coverage determination. Member specific benefits take precedence over medical policy.
- Application to Products: Policy is applicable to Sentara Health Plan Medicare products.
- Authorization Requirements: Pre-certification by the Plan is required.
- Special Notes:
    - This medical policy expresses Sentara Health Plan's determination of medically necessity of services, and they are based upon a review of currently available clinical information. Medical policies are not a substitute for clinical judgment or for any prior authorization requirements of the health plan. These policies are not an explanation of benefits.
    - Medical policies can be highly technical and complex and are provided here for informational purposes. These medical policies are intended for use by health care professionals. The medical policies do not constitute medical advice or medical care. Treating health care professionals are solely responsible for diagnosis, treatment and medical advice. Sentara Health Plan members should discuss the information in the medical policies with their treating health care professionals. Medical technology is constantly evolving and these medical policies are subject to change without notice, although Sentara Health Plan will notify providers as required in advance of changes that could have a negative impact on benefits.

References:

Specialty Association Guidelines; Government Regulations; Winifred S. Hayes, Inc; UpToDate; Literature Review; Specialty Advisors; National Coverage Determination (NCD); Local Coverage Determination (LCD).

LCD) Outpatient Psychotherapy L39853. (2024, 10). Retrieved 10 2025, from CMS: https://www.cms.gov/medicare-coverage-database/view/lcd.aspx?lcdid=39853&ver=3&keyword=mental%20health%20treatment&keywordType=all&areaId=all&docType=NCA,CAL,NCD,MEDCAC,TA,MCD,6,3,5,1,F,P&contractOption=all&sortBy=relevance&bc=1

(2025). Retrieved 10 2025, from MCG: https://careweb.careguidelines.com/ed29/index.html

Behavioral Health Integration Services. (2025, 4). Retrieved 10 2025, from CMS: https://www.cms.gov/files/document/mln909432-behavioral-health-integration-services.pdf

Clinical Social Workers to Receive Reimbursement for Digital Services. (2025). Retrieved 10 2025, from National Association of Social Workers: https://www.socialworkers.org/Practice/Tips-and-Tools-for-Social-Workers/Clinical-Social-Workers-to-Receive-Reimbursement-for-Digital-Services-in-2025

Digital mental health technologies. (2025). Retrieved 10 2025, from American Psychological Association (APA): https://www.apa.org/practice/digital-therapeutics-mobile-health

Digital therapeutics. (2025). Retrieved 10 2025, from Hayes: https://evidence.hayesinc.com/search?q=%257B%2522text%2522:%2522digital%2520therapeutics%2522,%2522title%2522:null,%2522termsource%2522:%2522pubmedchecker%2522,%2522page%2522:%257B%2522page%2522:0,%2522size%2522:50%257D,%2522type%2522:%2522all%2522,%2522s

DIGITAL THERAPEUTICS FOR MANAGEMENT AND TREATMENT IN BEHAVIORAL HEALTH. (2023). Retrieved 10 2025, from Substance Abuse and Mental Health Services Administration (SAMHSA): https://library.samhsa.gov/sites/default/files/pep23-06-00-001.pdf

Medicare Physician Fee Schedule Final Rule Summary: CY 2025. (2024, 11). Retrieved 10 2025, from CMS Document: https://www.cms.gov/files/document/r12975cp.pdf & https://www.cms.gov/files/document/mm13887-medicare-physician-fee-schedule-final-rule-summary-cy-2025.pdf

Policy Positions - Enabling Patient Access to Therapy/Advancing digital therapeutics. (2025). Retrieved 10 2025, from Digital Therapeutics Alliance: https://dtxalliance.org/advancing-dtx/dta-policy-positions/

Sleepio to treat insomnia and insomnia symptoms - Medical technologies guidance: MTG70. (2022, 1). Retrieved 10 2025, from National Institute for Health and Care Excellence (NICE): https://www.nice.org.uk/guidance/mtg70/chapter/1-Recommendations

Technology and the Future of Mental Health Treatment. (2024, 8). Retrieved 10 2025, from The National Institute of Mental Health (NIMH): https://www.nimh.nih.gov/health/topics/technology-and-the-future-of-mental-health-treatment

Academy Pushes for Coverage of Digital Therapeutics for Amblyopia Treatment. (2024, 5). Retrieved 11 2025, from American Academy of Ophthalmology (AAO): https://www.aao.org/advocacy/eye-on-advocacy-article/coverage-digital-therapeutics-amblyopia-treatment

Amblyopia. (2024, 11). Retrieved 11 2025, from National Eye Institute: https://www.nei.nih.gov/learn-about-eye-health/eye-conditions-and-diseases/amblyopia-lazy-eye

DTx Product Best Practices. (2019). Retrieved 11 2025, from Digital Therapeutics Alliance: https://dtxalliance.org/understanding-dtx/

What's New in Pediatric Ophthalmology Literature? (2025). Retrieved 11 2025, from American Association for Pediatric Ophthalmology and Strabismus (AAPOS): https://higherlogicdownload.s3.amazonaws.com/AAPOS/837b9651-77e2-c130-8e40-044fe6a5a2d3_file.pdf?X-Amz-Expires=3600&X-Amz-Security-Token=IQoJb3JpZ2luX2VjELH%2F%2F%2F%2F%2F%2F%2F%2F%2F%2FwEaCXVzLWVhc3QtMSJIMEYCIQC4omoP4xWyELdHnZR6EouYCP8jAPASSl2Al2ni1OA6GA

Synowiec, A., Stark-Inbar, A., Weinstein, M., Ironi, A., & Mauskop, A. (2024). One-Year Consistent Safety, Utilization, and Efficacy Assessment of Remote Electrical Neuromodulation (REN) for Migraine Treatment. Advances in therapy, 41(1), 170–181. Retrieved 11.6.2025. https://doi.org/10.1007/s12325-023-02697-6

(2025). Retrieved Nov 24, 2025, from Hayes - a symplr company: https://evidence.hayesinc.com/search?q=%257B%2522text%2522:%2522home%2520video%2520monitoring%2522,%2522title%2522:null,%2522termsource%2522:%2522searchbar%2522,%2522page%2522:%257B%2522page%2522:0,%2522size%2522:50%257D,%2522type%2522:%2522all%2522,%2522

Durable Medical Equipment (DME) - Chapter IV: Covered Services and Limitations. (2025, May 23). Retrieved Nov 24, 2025, from Virginia Department of Medical Assistance Services: https://vamedicaid.dmas.virginia.gov/sites/default/files/2025-05/DME%20Chapter%20IV%20%28updated%205.23.25%29_Final.pdf

Durable Medical Equipment. (2025). Retrieved Nov 24, 2025, from EviCore by Evernorth: https://www.evicore.com/provider/clinical-guidelines-details?solution=durable%20medical%20equipment&hPlan=AvMed

Moeller, J., Haider, H., & Hirsch, L. (2025, May 06). Video and ambulatory EEG monitoring in the diagnosis of seizures and epilepsy. Retrieved Nov 24, 2025, from UpToDate: https://www.uptodate.com/contents/video-and-ambulatory-eeg-monitoring-in-the-diagnosis-of-seizures-and-epilepsy?search=Sami%20Alert%20monitoring%20Epilipsy&source=search_result&selectedTitle=3~150&usage_type=default&display_rank=3#H1850292601

NCD: Durable Medical Equipment Reference List (280.1). (2025, Jun 09). Retrieved Nov 24, 2025, from Centers for Medicare and Medicaid Services: https://www.cms.gov/medicare-coverage-database/view/ncd.aspx?ncdid=190&ncdver=4&keyword=Durable%20Medical&keywordType=starts&areaId=all&docType=NCA,CAL,NCD,MEDCAC,TA,MCD,6,3,5,1,F,P&contractOption=all&sortBy=relevance&bc=1

Nelli System (Neuro Event Labs) for Seizure Detection. (2024, Jun 17). Retrieved Nov 24, 2025, from Hayes - a symplr company: https://evidence.hayesinc.com/report/pg.nelli

SAMi - The Sleep Activity Monitor. (2025). Retrieved Nov 24, 2025, from Avalon Healthcare Solutions: https://www.samialert.com/collections/sami-cameras

Seizure Alert and Detection Devices. (2025). Retrieved Nov 24, 2025, from Epilepsy Alliance America: https://epilepsyallianceamerica.org/seizure-movement-monitor-assistance/

Keywords:

Low-Intensity Therapeutic Ultrasound, LITUS, ZetrOZ System, Sustained Acoustic Medicine (SAM) and SAM PRO 2.0, Sam Sport, Ultrasonic therapy, Ultrasonic diathermy, PainShield, low-intensity continuous ultrasound (LICUS), low-intensity pulsed US (LIPUS), portable ultrasound, low frequency diathermy treatment devices. Actigraphy.