Sentara Health Plans

Medicaid

# Prescription Digital Therapeutics and Devices, Medical 259

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**All requests for authorization for the services described by this medical policy will be reviewed per Early and Periodic Screening, Diagnostic and Treatment (EPSDT) guidelines. These services may be authorized under individual consideration for Medicaid members under the age of 21-years if the services are judged to by medically necessary to correct or ameliorate the member's condition. Department of Medical Assistance Services (DMAS), Supplement B - EPSDT (Early and Periodic Screening, Diagnosis and Treatment) Manual.**

## 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:

- **Contraception based fertility awareness FDA approved or cleared mobile apps for** (e.g., Natural Cycles and federal preventive care mandates) are considered medically necessary when **ALL of the following** are met:
    - Mobile app is being used for contraception to prevent pregnancy
    - App has been prescribed by a treating provider
    - Member has medical contraindication for hormonal based contraception

- **Amblyopia Digital Therapy - Initial Use** - (for a 3 month period) when **ALL of the following** are met:
    - Individual is age 4 through 13 years (at least 4 years 0 days and less than 14 years old);
    - The individual has tried and failed 6 months of conservative treatments (i.e., full-time wear glasses, patching, Bangerter filter, and/or atropine penalization) (or contraindication/allergy/intolerance to atropine);
    - The individual has passed a dedicated 10 minute in-clinic performance ability test to assure suitable eye tracking performance (validity of eye tracking data > 90% and successful calibration process);
    - There is no history of light induced seizures;
    - Devises (RevitalVision, CureSight or Luminopia)

- **Amblyopia Digital Therapy - Continued Use** - (for every additional 3 month period) when **ALL of the following** are met:
    - The clinical records document adherence to therapy; and
    - The amblyopic visual acuity demonstrates continued improvement (note: when amblyopic visual acuity does not improve over two successive measurements at least 3 months apart, this requirement is not met).

- **Prescription Digital Therapeutics (PDTs) devices, software or mobile applications not addressed above** 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
- Canvas Dx autism diagnosis aid,
- 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
- Powered Exoskeletons (IE: IpsiHand, Motus Hand and Foot Robotic Assisted Devices)
- 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 |

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| 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 |

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| 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 Medicaid products.
- Authorization requirements: Pre-certification by the Plan is required.
- Special Notes:
    - Medicaid
        - This medical policy express Sentara Health Plan's determination of medically necessity of services, and they are based upon a review of currently available clinical information. These policies are used when no specific guidelines for coverage are provided by the Department of Medical Assistance Services of Virginia (DMAS). Medical Policies may be superseded by state Medicaid Plan guidelines. 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.
        - The Early and Periodic Screening, Diagnostic and Treatment (EPSDT) covers services, products, or procedures for children, if those items are determined to be medically necessary to "correct or ameliorate" (make better) a defect, physical or mental illness, or condition (health problem) identified through routine medical screening or examination, regardless of whether coverage for the same service or support is an optional or limited service under the state plan.

Children enrolled in the FAMIS Program are not eligible for all EPSDT treatment services. All requests for authorization for the services described by this medical policy will be reviewed per EPSDT guidelines. These services may be authorized under individual consideration for Medicaid members under the age of 21-years if the services are judged to by medically necessary to correct or ameliorate the member's condition. Department of Medical Assistance Services (DMAS), Supplement B - EPSDT (Early and Periodic Screening, Diagnosis and Treatment) Manual.

- Service authorization requests must be accompanied by sufficient clinical records to support the request. Clinical records must be signed and dated by the requesting provider withing 60 days of the date of service requested.

## References:

Including but not limited to: Specialty Association Guidelines; Government Regulations; Winifred S. Hayes, Inc; UpToDate; Literature Review; Specialty Advisors; National Coverage Determination (NCD); Local Coverage Determination (LCD).


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## 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.