Sentara® Health Plans

Medicaid

Wearable Monitoring and Treatment Devices, Medical 259

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Effective Date	8/1/2025
Next Review Date	5/2026
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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:

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

Low-Intensity Therapeutic Ultrasound (LITUS) Devices is a non-invasive, wearable device to deliver therapeutic ultrasound with long duration, low intensity waves to deep tissues, a pain treatment for home use.

Other common names for 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

Criteria:

Current role remains uncertain based on review of existing evidence. There are currently no clinical indications for this technology at home. Therefore, the following are considered **not medically necessary** for any clinical indication:

- Actigraphy
- Low-Intensity Therapeutic Ultrasound (LITUS) Devices

Document History:

Revised Dates:

- 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

Effective Date: January 2011

Coding:

Medically necessary with criteria:

Coding	Description
	None

Considered Not Medically Necessary:

Coding	Description
95803	Actigraphy testing, recording, analysis, interpretation, and report (minimum of 72 hours to 14 consecutive days of recording)
E1399	Durable medical equipment, miscellaneous
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
E0270	ComboCare E-Stim and Ultrasound Combo

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).

(NCD) Diathermy Treatment 150.5. (2006). Retrieved 2 2025, from CMS: https://www.cms.gov/medicare-coverage-database/view/ncd.aspx?ncdid=58&ncdver=2&bc=0

(2025). Retrieved 2 2025, from UpToDate: https://www.uptodate.com/contents/search?search=therapeutic%20ultrasound%20&sp=0&searchType=PLAIN_TEXT&source=USER_INPUT&searchControl=TOP_PULLDOWN&autoComplete=false

28th Edition. (2025). Retrieved 2 2025, from MCG: https://careweb.careguidelines.com/ed28/index.html

Clinical Guidelines. (2025). Retrieved 2 2025, from North American Spine Society (NASS): https://www.spine.org/Research/Clinical-Guidelines

Durable Medical Equipment (DME). (2025). Retrieved 2 2025, from DMAS: https://www.dmas.virginia.gov/for-providers/benefits-services-for-providers/long-term-care/services/durable-medical-equipment/

Low-Intensity Continuous Ultrasound for Treatment of Chronic Low Back Pain - Evidence Analysis Research Brief. (2024, 6). Retrieved 2 2025, from Hayes: https://evidence.hayesinc.com/report/earb.ultrasound5915

Therapeutic Ultrasound. (2025). Retrieved 2 2025, from American Institute of Ultrasound in Medicine (AIUM): https://www.aium.org/practice-topics/therapeutic-ultrasound?gad_source=1&gclid=EAIaIQobChMI_eLXmpjViwMV3EVHAR3biRmyEAAYAyAAEgI0I_D_BwE

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.