

Wearable Monitoring and Treatment Devices, Medical 259

Table of ContentDescription & DefinitionsCriteriaDocument HistoryCodingSpecial NotesReferencesKeywords

Effective Date	8/1/2025
<u>Next Review Date</u>	5/2026
<u>Coverage Policy</u>	Medical 259
<u>Version</u>	8

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:

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:

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Medically necessary with criteria:	
Coding	Description
	None
Considered Not Me	edically 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. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage of these services as it applies to an individual member.

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 Commercial products.

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- Authorization requirements: Pre-certification by the Plan is required.
- Special Notes:
 - \circ Commercial
 - 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.
 - Services mean both medical and behavioral health (mental health) services and supplies unless We specifically tell You otherwise. We do not cover any services that are not listed in the Covered Services section unless required to be covered under state or federal laws and regulations. We do not cover any services that are not Medically Necessary. We sometimes give examples of specific services that are not covered but that does not mean that other similar services are covered. Some services are covered only if We authorize them. When We say You or Your We mean You and any of Your family members covered under the Plan. Call Member Services if You have questions.

References:

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: <u>https://www.cms.gov/medicare-coverage-database/view/ncd.aspx?ncdid=58&ncdver=2&bc=0</u>

(2025). Retrieved 2 2025, from UpToDate:

https://www.uptodate.com/contents/search?search=therapeutic%20ultrasound%20&sp=0&searchType=PLAIN_T EXT&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): <u>https://www.spine.org/Research/Clinical-Guidelines</u>

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

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

Therapeutic Ultrasound. (2025). Retrieved 2 2025, from American Institute of Ultrasound in Medicine (AIUM): <u>https://www.aium.org/practice-topics/therapeutic-</u>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.