

Low-Intensity Therapeutic Ultrasound (LITUS) Devices

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<u>Coverage Policy</u>	DME 55
<u>Version</u>	3

Member specific benefits take precedence over medical policy. Coverage varies across plans. Coverage varies across plans. Refer to the individual’s benefit plan for coverage details.*

Purpose:

This policy addresses Low-Intensity Therapeutic Ultrasound (LITUS) Devices.

Description & Definitions:

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 for home use.

Criteria:

Low-Intensity Therapeutic Ultrasound (LITUS) Devices **does not meet the definition of medical necessity.**

Coding:

Medically necessary with criteria:

Coding	Description
	None

Considered Not Medically Necessary:

Coding	Description
E1399	Durable medical equipment, miscellaneous

Document History:

Revised Dates:

Reviewed Dates:

- 2023: March

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- 2022: March
- 2021: March

Effective Date:

- March 2020

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).

2019 American College of Rheumatology/Arthritis Foundation Guideline for the Management of Osteoarthritis of the Hand, Hip, and Knee. (2020, Feb). Retrieved Dec 29, 2022, from American College of Rheumatology/Arthritis Foundation: <https://www.rheumatology.org/Portals/0/Files/Osteoarthritis-Guideline-Early-View-2019.pdf>

(2022). Retrieved Dec 29, 2022, from HAYES:

https://evidence.hayesinc.com/search?q=%257B%2522text%2522:%2522LITUS%2522,%2522title%2522:null,%2522term%2522:%2522searchbar%2522,%2522page%2522:%257B%2522page%2522:0,%2522size%2522:50%257D,%2522type%2522:%2522all%2522,%2522sources%2522:%255B%2522*

Code of Federal Regulations Title 21 890.5300 Ultrasonic diathermy. (2022, Nov 29). Retrieved Dec 29, 2022, from FDA: <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm?ID=K211513>

DME Manual - Appendix B. (2022). Retrieved Dec 29, 2022, from DMAS DME:

<https://www.ecm.virginiamedicaid.dmas.virginia.gov/WorkplaceXT/getContent?impersonate=true&id={70DF587A-0000-CD19-9DA4-40F87C9CFC81}&vsId={BA20E884-FDDC-4BC0-8010-E14AAEE3F502}&objectType=document&objectStoreName=VAPRODOS1>

Innovative Soft Tissue Healing Treatments Now Available for Chronic Pain Sufferers in Virginia and Mid-Atlantic Region. (2022, Dec 14). Retrieved Dec 29, 2022, from GlobeNewswire: <https://www.globenewswire.com/news-release/2022/12/14/2573945/0/en/Innovative-Soft-Tissue-Healing-Treatments-Now-Available-for-Chronic-Pain-Sufferers-in-Virginia-and-Mid-Atlantic-Region.html>

National Coverage Determination (NCD) Heat Treatment, Including the Use of DIATHERMY and Ultra-Sound for Pulmonary Conditions. (Longstanding). Retrieved Dec 29, 2022, from Centers for Medicare & Medicaid Services NCD: <https://www.cms.gov/medicare-coverage-database/view/ncd.aspx?ncdid=4&ncdver=1&keyword=Diathermy&keywordType=starts&areald=all&docType=NCA,CAL,NCD,MEDCAC,TA,MCD,6,3,5,1,F,P&contractOption=all&sortBy=relevance&bc=1>

NCD Heat Treatment, Including the Use of Diathermy and Ultra-Sound for Pulmonary Conditions (240.3) Version 1 (N2403v1). (2022). Retrieved Dec 29, 2022, from MCG 26th Edition: <https://careweb.careguidelines.com/ed26/index.html>

NCD: DURABLE Medical Equipment Reference List - 280.1. (2005, May 5). Retrieved May 25, 2022, from CMS NCD: <https://www.cms.gov/medicare-coverage-database/view/ncd.aspx?ncdid=364&ncdver=1&keyword=Lung%20cancer%25>

Subacute and chronic low back pain: Nonpharmacologic and pharmacologic treatment. (2022, Aug 2). Retrieved Dec 29, 2022, from UpToDate: https://www.uptodate.com/contents/subacute-and-chronic-low-back-pain-nonpharmacologic-and-pharmacologic-treatment?search=ultrasonic%20diathermy&source=search_result&selectedTitle=6~125&usage_type=default&display_rank=6

Special Notes: *

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 Center for Medicare and Medicaid Services (CMS). Medical Policies may be superseded by National

or Local Coverage Determination (Medicare) 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 term DME is defined as equipment which, according to 42 CFR §414.202:

- Can withstand repeated use; i.e., could normally be rented and used by successive patients;
- Effective with respect to items classified as DME after January 1, 2012, has an expected life of at least 3 years;
- Is primarily and customarily used to serve a medical purpose;
- Generally, is not useful to a person in the absence of illness or injury; and,
- Is appropriate for use in a patient's home.

<https://www.cms.gov/medicare-coverage-database/view/ncd.aspx?NCDId=190>

Keywords:

SHP Low-Intensity Therapeutic Ultrasound (LITUS) Devices, SHP Durable Medical Equipment 55, ZetrOZ Systems, SAM Pro 2.0, tissue healing, therapeutic ultrasound, sustained acoustic medicine, LITUS, sam Sport, Ultrasonic therapy