PROVIDER POLICIES & PROCEDURES

VOLARA™ SYSTEM

The primary purpose of this document is to assist providers enrolled in the Connecticut Medical Assistance Program (CMAP) with the information needed to support a medical necessity determination for the Volara™ System for home use. By clarifying the information needed for prior authorization of services, HUSKY Health hopes to facilitate timely review of requests so that individuals obtain the medically necessary care they need as quickly as possible.

The Volara System is a respiratory device that provides continuous positive expiratory pressure to treat and prevent pulmonary atelectasis, continuous high frequency oscillation to mobilize retained secretions, and nebulized medication to help loosen secretions.

CLINICAL GUIDELINE

Coverage guidelines for the Volara System for home use are made in accordance with the DSS definition of Medical Necessity. The following criteria are guidelines *only*. Coverage determinations are based on an assessment of the individual and their unique clinical needs. If the guidelines conflict with the definition of Medical Necessity, the definition of Medical Necessity shall prevail. The guidelines are as follows:

The use of the Volara System in a home setting is considered **investigational and therefore not medically necessary** for all indications as there is insufficient published evidence supporting clinical efficacy and safety in the home.

NOTE: EPSDT Special Provision
Early and Periodic Screening, Diagnosis, and Treatment (EPSDT) is a federal Medicaid requirement that requires the Connecticut Medical Assistance Program (CMAP) to cover services, products, or procedures for Medicaid enrollees under 21 years of age where the service or good is medically necessary health care to correct or ameliorate a defect, physical or mental illness, or a condition identified through a screening examination. The applicable definition of medical necessity is set forth in Conn. Gen. Stat. Section 17b-259b (2011) [ref. CMAP Provider Bulletin PB 2011-36].

PROCEDURE

Prior authorization for the home use of the Volara System is required. Requests for coverage are reviewed in accordance with procedures in place for reviewing requests for durable medical equipment. Coverage determinations are based upon a review of requested and/or submitted case-specific information.

The following information is needed to review requests for home use of the Volara System:

1. Fully completed authorization request via on-line web portal; and
2. Documentation from the requesting physician supporting the medical necessity of the Volara System.

EFFECTIVE DATE

This policy for the prior authorization for home use of the Volara System for individuals covered under the HUSKY Health Program is effective July 1, 2021.

LIMITATIONS

Not Applicable

CODE:

Code	Description
E1399	Durable medical equipment, miscellaneous

DEFINITIONS

1. **HUSKY A**: Connecticut children and their parents or a relative caregiver; and pregnant women may qualify for HUSKY A (also known as Medicaid). Income limits apply.
2. **HUSKY B**: Uninsured children under the age of 19 in higher income households may be eligible for HUSKY B (also known as the Children's Health Insurance Program) depending on their family income level. Family cost-sharing may apply.
3. **HUSKY C**: Connecticut residents who are age 65 or older or residents who are ages 18-64 and who are blind, or have another disability, may qualify for Medicaid coverage under HUSKY C (this includes Medicaid for Employees with Disabilities (MED-Connect), if working). Income and asset limits apply.
4. **HUSKY D**: Connecticut residents who are ages 19-64 without dependent children and who: (1) do not qualify for HUSKY A; (2) do not receive Medicare; and (3) are not pregnant, may qualify for HUSKY D (also known as Medicaid for the Lowest-Income populations).
5. **HUSKY Health Program**: The HUSKY A, HUSKY B, HUSKY C, HUSKY D and HUSKY Limited Benefit programs, collectively.
6. **HUSKY Limited Benefit Program or HUSKY, LBP**: Connecticut's implementation of limited health insurance coverage under Medicaid for individuals with tuberculosis or for family planning purposes and such coverage is substantially less than the full Medicaid coverage.
7. **HUSKY Plus Physical Program (or HUSKY Plus Program):** A supplemental physical health program pursuant to Conn. Gen. Stat. § 17b-294, for medically eligible members of HUSKY B in Income Bands 1 and 2, whose intensive physical health needs cannot be accommodated within the HUSKY Plan, Part B.
8. **Medically Necessary or Medical Necessity**: (as defined in Connecticut General Statutes § 17b-259b) Those health services required to prevent, identify, diagnose, treat, rehabilitate or ameliorate an individual's medical condition, including mental illness, or its effects, in order to attain or maintain

   the individual's achievable health and independent functioning provided such services are: (1) Consistent with generally-accepted standards of medical practice that are defined as standards that are based on (A) credible scientific evidence published in peer-reviewed medical literature that is

generally recognized by the relevant medical community, (B) recommendations of a physician-specialty society, (C) the views of physicians practicing in relevant clinical areas, and (D) any other relevant factors; (2) clinically appropriate in terms of type, frequency, timing, site, extent and duration and considered effective for the individual's illness, injury or disease; (3) not primarily for the convenience of the individual, the individual's health care provider or other health care providers; (4) not more costly than an alternative service or sequence of services at least as likely to produce equivalent therapeutic or diagnostic results as to the diagnosis or treatment of the individual's illness, injury or disease; and (5) based on an assessment of the individual and his or her medical condition.

9. **Prior Authorization**: A process for approving covered services prior to the delivery of the service or initiation of the plan of care based on a determination by CHNCT as to whether the requested service is medically necessary.

REFERENCES

- Huynh TT, Liesching TN, Cereda M, et al. Efficacy of Oscillation and Lung Expansion in Reducing Postoperative Pulmonary Complication. *J Am Coll Surg*. 2019;229(5):458-466.e1. doi:10.1016/j.jamcollsurg.2019.06.004
- Nyland BA, Spilman SK, Halub ME, et al. A Preventative Respiratory Protocol to Identify Trauma Subjects at Risk for Respiratory Compromise on a General In-Patient Ward. *Respir Care*. 2016;61(12):1580-1587. doi:10.4187/respcare.04729

PUBLICATION HISTORY

Status	Date	Action Taken
Original Publication	June 2021	Approved by Medical Policy Review Committee on May 12, 2021. Approved at the June 21, 2021 CHNCT Clinical Quality Subcommittee meeting. Approved by DSS on June 28, 2021.
Reviewed	June 2022	Reviewed and approved without changes at the May 11, 2022 CHNCT Medical Reviewer meeting. Reviewed and approved without changes by the CHNCT Clinical Quality Subcommittee on June 20, 2022. Approved by DSS on July 5, 2022.
Updated	June 2023	Added “and safety in the home” to statement: “The use of the Volara System in a home setting is considered investigational and therefore not medically necessary for all indications as there is insufficient published evidence supporting clinical efficacy and safety in the home”. Change approved at the May 10, 2023, CHNCT Medical Reviewer meeting. Changed approved by the CHNCT Clinical Quality Subcommittee on June 19, 2023. Approved by DSS on June 28, 2023.