



State of California-Health and Human Services Agency
Department of Health Services



ARNOLD SCHWARZENEGGER
Governor

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Index: Benefits

TO: ALL CALIFORNIA CHILDREN'S SERVICES (CCS) COUNTY ADMINISTRATORS, MEDICAL CONSULTANTS, AND STATE CHILDREN'S MEDICAL SERVICES (CMS) BRANCH STAFF AND REGIONAL OFFICE STAFF

SUBJECT: AUTHORIZATION OF RENTAL OF PORTABLE HOME VENTILATORS PURPOSE

This numbered letter provides county CCS programs and CMS Branch Regional Offices with guidelines for authorizing the rental of portable home ventilators and accessories and backup ventilators. This numbered letter supercedes all previous instructions regarding requests for authorization of ventilators.

BACKGROUND

Introduction

Ventilatory support may be required for the treatment of conditions that result in severely impaired respiratory function including chronic lung disorders, anatomical abnormalities of the chest, neuromuscular disorders, head and spinal cord injury, upper airway obstruction, and disorders of the respiratory control center. The level of ventilatory support varies from intermittent use of continuous positive airway pressure (CPAP) in clients who retain spontaneous respiratory drive and have normal lung function, to ventilatory support in clients who have no spontaneous respirations. Some clients have reversible conditions (such as infants with chronic lung disease) and will require home ventilation for a limited period of time. Others have irreversible conditions (such as progressive neuromuscular conditions) and will require ventilatory support for the rest of their lives.

Portable home ventilators are classified as durable medical equipment. Portable home ventilators are only rented and may not be purchased. Durable Medical Equipment

(DME) vendors are responsible for servicing ventilators and are required to employ a licensed respiratory care practitioner who is available around the clock seven days a week to care for ventilator emergencies. It is expected that they can give immediate phone support and be able to arrive at a client's home in no more than 2-3 hours for emergencies. In addition, all caregivers of ventilator dependent clients must be skilled in basic CPR and capable of providing adequate manual respiration when necessary.

CPAP, BiPAP (bi-level positive airway pressure), BiPAP-St, and intermittent percussive ventilator devices (IPV, Impulsator) are not considered ventilators. Therefore, these devices are not addressed in this policy letter.

Ventilators for home use are classified as volume ventilators or pressure support ventilators with pressure control feature. Volume ventilators are usually simpler in design, have fewer controls, and are not designed to interact well with the spontaneously breathing patient. In contrast, the pressure support ventilators usually have more sophisticated designs that allow much finer control of respiratory support, including optimal interaction with the spontaneously breathing patient. Pressure support ventilators are smaller, more portable and more costly.

Volume Ventilators

Portable volume ventilators currently in use include the LP-10 (Malinckrodt), PLV-100 (Respironics) and the LTV-800 (Pulmonetic Systems Inc.). These ventilators deliver a selected inspiratory volume and set pressure. While they incorporate a safety release valve to control maximum pressure, the pressure is not continuously variable in response to varying inspiratory resistance and pressure requirements of the patient. As a result, the ventilator may deliver excessive pressure, and over time may contribute to the development of lung damage due to barotrauma. In addition, volume ventilators do not have a continuous flow feature to maintain positive end-expiratory pressure (PEEP). Although, these ventilators may deliver CPAP with the use of an add-on system, this method is not FDA approved for invasive (tracheostomy) CPAP.

Most volume ventilators for home use are large, heavy, and limit mobility. However, the LTV 800 volume ventilator is lightweight and portable. Therefore, this model is useful for pediatric clients who do not require pressure support or pressure control, but can benefit from the lightweight portability. Despite, the disadvantages of volume ventilators, they remain the option of choice for some older children and adolescents.

Pressure Support Ventilators

The pressure support ventilators, including the LTV900, the LTV950, (Pulmonetics Corp.) and the Newport HT50, (Newport Corp.), have features that are well suited to support of infants, patients with weak respiratory muscles, and patients with chronic

severe lung disease. In addition, they are compact and lightweight and, therefore, allow maximum independence in the community or school. These ventilators are only a benefit of the Medi-Cal program when authorized by CCS.

These pressure control ventilators have a pressure support feature. Pressure support results from the continuous airflow through the ventilator circuits during the entire respiratory cycle. This allows the patient to generate a larger tidal volume with each spontaneous breath. Because the inspiratory triggering mechanism is located at the proximal level of the circuit tubing (close to the patient), there is less effort required to trigger a breath. This is an especially good feature for patients with weak respiratory muscles, patients with severe chronic lung disease, and for patients who are in a ventilator weaning program. Similarly, the continuous airflow of pressure support allows the delivery of PEEP and enables the ventilator to deliver CPAP assisted ventilation without additional equipment.

The pressure control feature of these ventilators allows for adequate chest expansion that is controlled by the pressure generated as opposed to a set tidal volume. Set tidal volumes may not deliver the true required tidal volume to a patient if there is a sudden change in airway resistance or respiratory system compliance. This is especially true in infants. Pressure controlled ventilation is also advantageous for clients who require high inspiratory pressures intermittently such as during seizure episodes or posturing. Finally, these ventilators are also useful for patients who have a history of inconsistent or inadequate volume delivery due to variable air leaks around the tracheostomy.

Ventilator weaning

It is essential that the plan of weaning of the pediatric patient with potentially reversible disease from ventilator support be addressed on a regular periodic basis. The pulmonologist should evaluate these patients at least every six months.

Backup ventilators

Though a relatively rare occurrence, ventilators may fail for reasons that include equipment malfunction or caregiver error. Therefore, a functioning backup ventilator must be in the home if the client requires ventilatory support for 16 or more hours a day or if the client lives more than 50 miles or 2 hours travel time from medical and technical support.

POLICY

- I. Rental of portable home ventilators is a benefit of the CCS Program for CCS clients, regardless of payor source, when determined to be medically necessary for the

management of a CCS medically eligible condition or the complications of that condition.

- II. Rental of a portable volume home ventilator may be authorized for any client who requires mechanical ventilatory support.
- III. Rental of a pressure support portable home ventilator may be authorized when the medical records document that the client meets any of the following medical criteria:
 - A. The client is less than 5 years old and requires ventilatory support for any portion of the day.
 - B. There is difficulty with management of ventilatory requirements because of large air leaks around the tracheostomy site.
 - C. The client requires unusually high airway pressures (> 30 cm H₂O) to adequately expand his/her lungs.
 - D. The client has spontaneous respiratory ability but weak respiratory muscles and requires pressure support to reduce the ventilator associated work of breathing and avoid respiratory muscle fatigue.
 - E. The client has been managed on a pressure support ventilator prior to becoming a CCS client and the requesting physician has determined the client cannot be transitioned to a portable volume ventilator.
 - F. The client requires invasive (via tracheostomy) CPAP or PEEP support for any portion of the day.
- IV. Requests for authorization of rental of any ventilator must come from the CCS approved Pulmonary SCC Pulmonologist, or the CCS approved neonatologist, intensivist, or physiatrist who is authorized to provide pulmonary care for the client.
- V. Rental of a stand-by back-up ventilator for emergency use should be authorized at the same time the rental of a portable home ventilator is authorized. Some clients develop progressive disease and require a backup ventilator sometime after hospital discharge. Rental of a stand-by back-up ventilator for emergency use may be authorized for either of the following conditions:

1. The client requires 16 or more hours of ventilatory support a day; or
 2. The client lives more than 50 miles or 2 hours travel time from medical and technical support.
- VI. Authorization of the ventilator is based on the criteria stated in Policy I.-V. CCS programs should authorize the ventilator once these criteria are met.
- VII. Requests for authorization of rental of ventilators for individuals with commercial health insurance coverage through an Health Maintenance Organization (HMO) must include documentation that home ventilators are an excluded benefit of the plan. Management of the ventilator must be directed through a CCS approved pulmonologist. A local pulmonologist associated with the HMO may be authorized to provide care, if so delegated by the pulmonary SCC medical director and there is clear documentation of care coordination between the two physicians.
- VIII. The CCS program's case management role includes ascertaining that the hospital has performed appropriate discharge planning including the following:
- A. Documentation that a SCC home ventilator outpatient clinic visit or similar SCC pulmonary clinic visit has been arranged for no more than two weeks following an inpatient stay and at least every four months thereafter.
 - B. The availability of the home caregiver around the clock, with reasonable respite and emergency caregiver coverage.
 - C. Prior to hospital discharge of the CCS client, there has been training of all caregivers on the use of the actual ventilator the client will use in the home, basic CPR training and documentation that the caregivers have demonstrated ability to provide mechanical respiratory support for the client when necessary.
 - D. In-hospital involvement of the DME vendor's licensed respiratory care practitioner who will provide in-home service of the client's ventilator.
 - E. Arrangements for in-home shift nursing care where available (e.g. referral to Medi-Cal in Home Operations for Medi-Cal beneficiaries) and if necessary.

POLICY IMPLEMENTATION

- I. The CCS independent county Medical Consultant, or designee, or the Regional Office Medical Consultant shall review all requests for authorization of rental of all types of portable home ventilators.
- II. Documentation submitted with the Service Authorization Request (SAR) must include the following:
 - A. The initial request for authorization of ventilators requires the most recent consultation note by the appropriate SCC physician that includes:
 1. The client's diagnosis and the rationale for mechanical ventilatory support;
 2. the client's ventilator settings,
 3. the type of ventilator requested, and
 4. the ventilator model requested.
 - B. Requests for reauthorization of ventilators are required every 12 months and shall be accompanied by a client evaluation by the CCS approved pulmonologist within the previous four months that documents the following:
 1. The client's diagnosis and the rationale for mechanical ventilatory support;
 2. Determination of whether the client has either an irreversible condition or potentially reversible condition. If the client has a potentially reversible condition, the report must include a description of the plan for weaning ventilatory support;
 3. The client's ventilator settings;
 4. the type of ventilator requested; and
 5. the ventilator model requested.

- III. Portable home ventilators are to be authorized as a DME rental only. They are not to be purchased.
 - A. Authorization of rental of volume ventilators requires the use of Health Care Procedure Coding standardization/System (HCPCS) code E0450.
 - B. Authorization of rental of pressure support ventilators requires the use of HCPCS code E0463.
 - C. Rental of ventilators shall be for a period of one year or to the end of the CCS client's eligibility.
 - D. Authorization of a back-up ventilator must be listed as a separate line item on the SAR and "back-up" must be stated.
- IV. Ventilator accessories required for the operation of the ventilator are included in the rental reimbursement and, therefore, should not be separately authorized. These accessories include circuits, tubing, valves, filters, batteries, cables, ventilator stands, and wheelchair attachments.
- V. Ventilator heaters and humidifiers, if prescribed by the physician can be separately authorized. Tracheostomy care supplies and oxygen delivery supplies are also authorized separately.
- VI. Respiratory Care Practitioner services for home ventilator clients are the responsibility of the DME vendor and should not be separately authorized.

Note: CCS policy on the timeline for action on requests for authorization of services was promulgated in Numbered Letter 20-0997 dated September 10, 1997, as follows:

Within five working days from the receipt of a request for service by the CCS program, the medical consultant/designee must decide whether to approve, deny, or modify a request for CCS-eligible client or defer the request for additional information.

Original Signed by Marian Dalsey, M.D., M.P.H.

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Enclosures:

Home Ventilator Discharge Planning Checklist
(for use at the discretion of the County)
Home Ventilator Reauthorization Checklist
(for use at the discretion of the County)
Portable Ventilator Descriptions
References

HOME VENTILATOR DISCHARGE PLANNING CHECKLIST

It is the expectation of the CCS Program that the Special Care Center or Discharging Facility will complete the following steps in an effort to ensure a safe home environment for the ventilated child.

Client's name: _____

Client's DOB: _____ **Client's CCS number:** _____

Discharging Facility: _____

Home Ventilation Clinic or Pulmonary Special Care Center for outpatient services:

- Home Ventilation Clinic or Pulmonary Special Care Center clinic visit arranged for no more than 2 weeks following an inpatient stay.
Appointment date: _____
- Home Ventilation Clinic or Pulmonary Special Care Center Outpatient clinic visit arranged for every 3-4 months.
- Home caregiver around the clock. Describe arrangements: _____

- Reasonable respite and emergency caregiver coverage
- Training of all caregivers on the use of the actual ventilator the client will use in the home.
- Current basic CPR training of all caregivers.
- Caregivers have demonstrated ability to provide mechanical respiratory support for the client when necessary.
- The DME vendor's licensed respiratory care practitioner, who will provide the in-home service of the client's ventilator, has met the child and family and has participated in the family training in the inpatient setting.

Check one of the following bullet points:

- In-home shift nursing care is required at the following level (hours per day, licensure of the nurse): _____
- In-home shift nursing care is not required, or is not available and safe alternative caregivers have been identified. Please describe: _____

Person Completing Form: _____

Physician Signature: _____

Requirements based on PEDIATRIC HOME VENTILATORS: DISCHARGE PLANNING AND AFTER
DISCHARGE MANAGEMENT GUIDELINES

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HOME VENTILATOR REAUTHORIZATION CHECKLIST

Requests for reauthorization of ventilators are required every 12 months.

Client's name: _____

Client's DOB: _____ **Client's CCS number:** _____

Date: _____

Home Ventilation Clinic or Pulmonary Special Care Center for outpatient services:

Date of Clinic Evaluation (must be within the previous 4 months): _____

What is the client's diagnosis and the rationale for mechanical ventilatory support?

Does the client have a potentially reversible condition?(circle one) Yes / No

If yes, describe the plan for weaning ventilatory support.

Current Ventilator settings: _____

Type of ventilator requested. (circle one) Volume Limited / Pressure Limited

Ventilator Model Requested: _____

Person Completing Form: _____

Physician Signature: _____

Portable Ventilators with invasive interface (intubation or tracheostomy)

Brand Name	LTV 950	LTV 900	Newport HT50	LTV-800	LP-10	PLV-100
Manufacturer	Pulmonetic Systems, Inc	Pulmonetic Systems, Inc	Newport Medical Instruments	Pulmonetic Systems, Inc	Mallinckrodt	Respironics
Website	http://www.pulmonetic.com	http://www.pulmonetic.com	http://www.newportnmi.com	http://www.pulmonetic.com	http://www.puritanbennett.com	http://plv100.respironics.com
HCPCS Code	E0463	E0463	E0463	E0450	E0450	E0450
Monthly Rental	\$1,150	\$1,150	\$1,150	\$650	\$650	\$650
Dimensions (H x W x D)	3 in x 10 in x 12 in	3 in x 10 in x 12 in	10.24 in x 10.63 in x 7.87 in	3 in x 10 in x 12 in	9.75 in x 14.5 in x 13.25 in	9 in x 12.25 in x 12.25 in
Weight	13.4 lbs	13.4 lbs	15 lbs	12.85 lbs	35 lbs	28.2 lbs
Portability	maximum	maximum	maximum	maximum	limited	limited
Volume Limited Machine Breaths	Yes Control, Assist/Control, SIMV	Yes Control, Assist/Control, SIMV	Yes Assist/Control, SIMV	Yes Control, Assist/Control, SIMV	Yes Assist/Control, SIMV	Yes Control, Assist/Control, SIMV
Pressure Limited Machine Breaths	Yes Control, Assist/Control, SIMV	No	Yes Assist/Control, SIMV	No	Yes Pressure Limited (fixed flow)	No
Pressure Support for Spontaneous Breaths	Yes adjustable rise time and flow termination	Yes adjustable rise time and flow termination	Yes	No	No	No
Adjustable Trigger Sensitivity	Yes "Flow"	Yes "Flow"	Yes "Pressure"	Yes "Pressure"	Yes "Pressure"	Yes "Pressure" (limited control)
PEEP	Yes	Yes	Yes	Yes	No	No
CPAP	Yes	Yes	Yes	add on system NOT FDA approved	add on system NOT FDA approved	add on system NOT FDA approved
Age Range	Pediatric - Adult	Pediatric - Adult	Pediatric - Adult	Pediatric - Adult	Pediatric - Adult	Pediatric - Adult
Patients under 10 Kg	**	**	No	*	No	*
Patients with large air leaks around tracheostomy	**	**	**	*	*	*
Patients with intermittently high airway pressures	**	**	**	*	*	*
Patients with weak respiratory muscles	**	**	**	*	*	*
Patients with no spontaneous respirations	*	*	*	**	**	**
* = good		** = better				

REFERENCES

Textbook of Pediatric Intensive Care Mark C Rogers ed., 3rd Edition

Hall, J and Wood, L Liberation of the Patient From Mechanical Ventilation. JAMA
3/27/87 p 1621-1628

Tobin MJ, Current Concepts: Mechanical Ventilation N Engl J Med 1994;330:1056-1061

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