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Index: Durable  
Medical Equipment

TO: All County California Children Services (CCS) Offices, State Regional Children's Medical Services (CMS) Regional Offices, Genetically Handicapped Persons Program (GHPP), and State CMS Staff

SUBJECT: AUTHORIZATION OF FLUTTER VALVES AND ThAIRapy VESTS

A. INTRODUCTION

The Scandipharm FLUTTER valve and the American Biosystems ThAIRapy Vests have become benefits for selected patients under the Medi-Cal program. The purpose of this numbered letter is to delineate policy guidelines for the authorization of these products for both CCS and GHPP clients. These guidelines are effective as of the date of this numbered letter.

B. DISCUSSION

The FLUTTER is a hand-held device that resembles a pipe with a plastic circular cone containing a stainless steel ball. The patient blows into the mouthpiece causing the steel ball to move up and down inside the chamber; this creates internal vibrations or fluttering of the patient's air columns and airway walls. These vibrations aid in loosening and the clearing of thick mucous facilitating airway and lung clearance. The device is inexpensive, small, easily transportable, can be used in any environment, and is without adverse side effects in most patients. The device may be used either alone or in combination with chest physiotherapy, however, it does require active relatively forceful expiratory effort by the patient. It is distributed in the United States exclusively by Scandipharm, Inc. of Birmingham, Alabama.

The ThAIRapy Vest is a high-frequency chest compression (HFCC) device for which there is less information regarding efficacy and optimal usage. Published literature indicates that there is no significant difference in short-term efficacy between conventional postural drainage, positive end-expiratory pressure physiotherapy, and HFCC physiotherapy in patients with cystic fibrosis (CF) who are hospitalized for an acute

pulmonary exacerbation. The ThAIRapy Vest, which is a HFCC device, consists of an individually fitted vest containing air chambers that are connected to a portable machine which generates high frequency air vibrations. These vibrations are transmitted through the external chest wall to the patient's lungs and pulmonary air columns achieving an effect similar to the FLUTTER valve or to external chest wall manipulation. This system is passive, requires little patient effort, does not require a second person to do manual chest physiotherapy, and has the capacity to monitor patient compliance. It is, however, significantly larger and is not portable, it is vastly more expensive than the FLUTTER valve. Special fitting is required for the vest portion, and the compressor requires electrical input. The ThAIRapy Vest is a product of American Biosystems, St. Paul, Minnesota.

C. POLICY

1. FLUTTER valves are a benefit of the CCS program, and may be authorized for purchase, when all of the following are met:
  - a. They are prescribed by a CCS paneled physician who is a member of the authorized CCS/GHPP Cystic Fibrosis (CF) and Pulmonary Disease Special Care Center (SCC).
  - b. The beneficiary has a CCS/GHPP eligible condition, such as CF, with the inability to adequately mobilize intrapulmonary secretions.
  - c. The beneficiary/caretaker can receive adequate training on its use by CCS/GHPP SCC staff or their designees.
2. The ThAIRapy vest is a benefit of the CCS and GHPP programs when all of the following are met:
  - a. It is prescribed by a CCS/GHPP paneled physician who is a member of the authorized CCS/GHPP CF and Pulmonary Disease SCC.
  - b. The beneficiary has a CCS/GHPP eligible condition, such as CF, with the inability to adequately mobilize intrapulmonary secretions.
  - c. A caretaker/guardian is not available to perform chest physiotherapy on a routine basis.
  - d. The equipment is for use in the CCS/GHPP beneficiary's place of residence.

- e. Conventional chest physiotherapy has been shown to be inadequate to meet the patient's medical needs.
- f. There are no medical contraindications to the use of the Vest.

**And** at least one of the following conditions is met:

- g. The beneficiary has had an adequate trial of at least six-to-eight weeks of FLUTTER valve use, including documentation of training in proper use and technique, and compliance with at least daily utilization, without demonstrable benefit.
- h. The beneficiary has documented insufficient respiratory muscle strength to utilize a FLUTTER valve effectively.
- i. The beneficiary has another medical condition which precludes the use of a FLUTTER valve.

#### D. POLICY IMPLEMENTATION

- 1. The determination of medical necessity of authorizations of the FLUTTER valve or the ThAIRapy Vest is the responsibility of the CCS Medical consultant or designee, following review of SCC reports and prescriptions.
- 2. For those patients who cannot use the FLUTTER valve or who do not demonstrate adequate response, the determination of medical necessity for the authorization of a ThAIRapy Vest should include:
  - a. Documentation of the lack of availability of parent/guardian/caretaker to provide chest physiotherapy, or
  - b. Determination of the length of time a parent/guardian/caretaker will not be available to provide chest physiotherapy.  
**and**
  - c. Documentation that conventional chest physiotherapy is insufficient to meet the patient's medical needs.
- 3. The authorization for the ThAIRapy Vest should include:

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- a. Purchase of the vest.
  - b. Rental of the compressor machine, along with a servicing and maintenance agreement.
  - c. An initial time limitation of two months for the compressor, after which the authorization may be renewed for a longer time period. Authorizations for renewal of the equipment should be dependent upon documentation of compliance demonstrating a minimum of at least daily use.
  - d. Purchase of the compressor may be considered only:
    - 1) after 3.c. above is met, and
    - 2) if the patient can be expected to utilize the equipment for an extended period of time, i.e., greater than one year.
4. Both the ThAIRapy and the FLUTTER valve are Medi-Cal benefits. The billing code both the ThAIRapy vest and the FLUTTER valve is "by report" E1399. The billing must be accompanied by a copy of the catalog description of the product.

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