

Noninvasive Positive Pressure RADs for COPD (#CAG-00052N) Meeting Report

Purpose: The purpose of the meeting was to listen to information presented by the representatives experts on the effective use of RADs for a small subgroup severely ill COPD patients in the home.

Date: April 25, 2000

Place: HCFA Central Office, Baltimore, Md.

Participants:

HCFA: Hugh Hill, MD, Madeline Ulrich, MD, John Whyte, MD, Betty Shaw, Lorrie Ballantine, Dorothy Honeman, and Francina Spencer,

Outside Representatives: Aselu Cuervo, Bruce Fried, Jacquelyn McClure, DeLynn Johnston, Steven Stranne, Marcia Nusgart, Mary Hirsch, Bill Wood, and via speakerphone; Nicholas S. Hill, MD, Gerard J. Criner, MD

Summary: Representatives of the Coalition of Respiratory Care and the American Association of Homecare requested this meeting to discuss use of RADs with backup rate in the home for a small subgroup of very severely ill COPD patients. The represented groups are seeking relief from the requirement that patients undergo a three month trial on a RAD without backup rate before one with backup rate may be approved. The particular small subgroup of COPD patients for whom they wish relief are those who have been discharged to home after prolonged hospitalization during which they required use of an RAD with backup rate for an extended period.

HCFA explained that the coverage process was evidenced based, i.e., medical evidence is required to support coverage changes. The requesting groups agreed to submit evidence necessary to support the need for the proposed change. Also they will work with the durable medical equipment regional carriers (DMERCS) to clarify issues related to the use of a polysomnogram as evidence for the need of a RAD for COPD patients.

(NOTE: The February 7, 2000, posting contains an error. The second paragraph, first sentence after item 4 should read, "The RMRP for RAD used for COPD patients requires among other things, prior to initiating therapy, OSA (and treatment with CPAP) has been considered and ruled out.")

Next Steps:

While the requestors who have met and corresponded with us, as outlined above, have promised to submit supporting documentation for their position, we hope for broader input. HCFA requests that all

parties with information send evidence demonstrating a benefit and delimiting a population, wherein severely ill COPD patients should have direct placement on an NPPV ventilator with backup rate without first having a trial of a respiratory assist device without a backup rate.

1. We are interested in receiving scientific evidence associating a subset of severely ill patients, as defined by clinical criteria, with an outcome benefit from initiation of a device with a backup rate without a preceding trial of a RAD without a backup rate. We seek evidence that shows benefit over and above that achieved by backup rate device use after trial.
2. Evidence relating to an appropriate duration of trial and criteria for determining success or failure thereof is also solicited. If a trial is undertaken, under what conditions should it be terminated before its scheduled completion?

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