IMPLEMENTATION INSTR: ISSUE OF MEDICAL EQPT PRESCRIBED FOR ECHS MEMBERS

1. Ref
   (a) GOI/MoD letter No 24(8)/03/US(WE)/D(Res) dated 19 Dec 03.
   (b) Cent Org ECHS Letter No B/49773/AG/ECHS dated 05 Apr 04.
   (c) CGHS OM No S11011/4/2014-CGHS(P) dated 05 Mar 14.

2. The issue of medical equipment prescribed for ECHS members is governed by GOI/MoD letter under reference 1(a). The procedure for issue has been implemented vide Central Org ECHS letter under reference 1(b). MH& FW OM No 24-2/96/R&H/CGHS/Part-II CGHS(P) dt 26 Jun 01 governs the type of equipment to be issued and its ceiling rates. This OM has been updated by CGHS OM under reference 1(c). However, this OM has authorized additional types of equipment without formulating the prescription criteria for the same. The matter has been considered by this Central Org in consultation with O/o DGAfMS and Consultant, Respiratory Medicine, AH R&G and this implementation letter is being issued suitably modified to cater for the needs and procedures of ECHS and its members.

3. The following guidelines have been framed for issue of Oxygen Concentrator/BiPAP/CPAP etc. to ECHS beneficiaries:
   (a) The items will be procured by Polyclinic and issued to beneficiary as per procedure and conditions outlined in Central Org letter under reference 1(b).
   (b) Statement of case should be accompanied with the relevant Proforma for the machine, duly filled up by the treating physician (specimen copy of Proforma attached). The treating physician should carefully read the laid down guidelines before filling up the respective columns of the Proforma. Actual value of the parameters mentioned in Proforma should invariably be entered and complete basic investigation reports must be attached.
(c) The maximum ceiling limit for procurement will be as following:
   (i) Oxygen Concentrator  Rs. 60,000/-
   (ii) CPAP                  Rs. 50,000/-
   (iii) Bi-level CPAP        Rs. 80,000/-
   (iv) Bi-level Ventilatory system  Rs. 1,20,000/-

(d) The above ceiling limits include cost of maintenance with spare parts for a period of five years. Humidifiers, if prescribed should be an integral part of the PAP system rather than being supplied separately.

4. Reimbursement is NOT permitted as of date. Instr for reimbursement are being issued separately. This office letter No B/ 49761/AG/ ECHS/ Policy dated 27 Jan 14 maybe treated as cancelled.

5. These instructions and rates shall take effect from the date of issue of this letter. This letter is issued with approval of competent authority empowered vide GOI/Mod letter No.22(1)/ 01/ US(WE)/ D(Res) dated 30 Dec 02 amended vide GOI/Mod letter No.22(1)/ 01/ US(WE)/ D(Res) dated 29May 03.

Encl: 1. Proforma for prescription
   2. Notes to Prescribers

   (Vijay Anand)
   Col
   Dir (Med)
   For MD ECHS

Copy To:
DOESW - for info.
DGAFMS-DG-3A
DGMS Army)/DGMS-5(B)
DGMS (Navy)/Dir ECHS (Navy)
DGMS (Air Force) (Med-7) - for info please.

UTI-ITSL
1533/1, Above Farico Show Room
1st Floor, Old Madras Road Halasuru,
Bangalore, Karnataka-560008

Office of the CGDA
Ulan Batar Road, Palam, Delhi Cantt-10

(All Regional Centres) - Request confirm receipt and ensure action.

Internal
Ops & Coord, P &FC, Claim Sec
Stats & Automation Sec - for uploading on ECHS website of said letter.
NOTE FOR PRESCRIBERS
(For diagnostic as well as for titration)

Only whole night manually validated Level-I polysomnography including channels for sleep, breathing, pulse oxymetry, leg EMG, ECG, snoring & BI-LEVEL titration will be accepted for consideration of BI-LEVEL CPAP / BI-LEVEL ventilator support system. Screening studies such as Level III, Level IV (Cardio pulmonary sleep studies) shall not be acceptable. Auto titrated CPAP studies shall also not be acceptable.

DEFINITIONS

1. **Apneas** Absence of airflow on the nasal cannula and < 10% baseline fluctuations on the thermistor signal, lasting for > 10 s.

2. **Flow limitation Events:** Any series of two or more breaths (lasting > 10 s) that had a flattened or nonsinusoidal appearance on the inspiratory nasal cannula flow signal and ended abruptly with a return to breaths with sinusoidal shape.

3. **Hypopneas** American Academy of Sleep Medicine (AASM) hypopneas: As proposed by the AASM Task Force (10), these events include both flow Hypopneas and any flow limitation event associated with 3% desaturation or associated with an AASM arousal.

4. **RERA (respiratory effort-related arousal) is defined as a event characterized by increasing respiratory effort for ≥ 10 seconds leading to arousal from sleep but which does not fulfill the criteria for hypopnea or apnea. A RERA is detected with nocturnal esophageal catheter pressure measurement, which demonstrates a pattern of progressive negative esophageal pressures terminated in a change in pressure to a less negative pressure level associated with an arousal.**

5. **RDI (respiratory distress index) is defined as the number of obstructive apneas, hypopneas and RERA’s per hour (based on a minimum of 2 hours of sleep in case of split-NPSG) recorded by polysomnography using actual recorded hours of sleep (i.e. the RDI may not be extrapolated or projected).**

6. **AHI (Apnea Hypopnea Index)** The AHI is equal to the average number of episodes of apnea and hypopnea per hour and must be based on a minimum of two hours of sleep recorded by polysomnography using actual recorded hours of sleep, (i.e., the AHI may not be extrapolated or projected).

   **Note:** For the purposes of this recommendation, the terms apnea hypopnea index (AHI) and respiratory disturbance index (RDI) are interchangeable, although they may differ slightly in clinical use; an AHI/RDI greater than 30 is consistent with severe obstructive sleep apnea. In some cases, respiratory effort-related arousals (or RERAS) are included in the RDI value. These RERA episodes represent EEG arousals associated with increased respiratory efforts but do not qualify for apneic or hypopneic episodes because of the absence of their defining air flow changes and/or levels of oxygen saturation.

7. **Upper airway resistance syndrome (UARS):** is an abnormal breathing pattern during sleep that is associated with isolated daytime sleepiness not explained by
any other cause, including the obstructive sleep apnea/hypopnea syndrome. Essential features include (a) the clinical complaint of excessive daytime sleepiness; (b) an elevated EEG arousal index (more than ten per hour of sleep) with arousals related to increased respiratory efforts as measured by continuous nocturnal monitoring of esophageal pressures; (c) a normal RDI of less than 5 events per hour of sleep. Supportive features include (a) the clinical complaint of snoring (b) an increase in snoring intensity prior to EEG arousals and (c) clinical improvement with a short term trial of nasal CPAP therapy.

8. **Split-Night Study NPSG:** Patients with a RDI of > 40 events per hour during the first 2 hours of a diagnostic NPSG receive a split-night study NPSG, of which the final portion of the NPSG is used to titrate CPAP; split-night study may be considered for patients with RDI of 20-40 events per hour, based on clinical observations, such as the occurrence of obstructive respiratory events with a prolonged duration or in association with severe oxygen desaturation: a minimum of 3 hours of sleep is preferred to adequately titrate CPAP after this treatment is initiated; split-night studies require the recording and analysis of the same parameters as a standard diagnostic NPSG; on occasion, and additional full-night CPAP titration NPSG may be required if the split-night study did not allow for the abolishment of the vast, majority of obstructive respiratory events or prescribed CPAP treatment does not control clinical symptoms.

**INDICATIONS**

1. **CPAP treatment is indicated in the following situations:**
The treatment of obstructive sleep apnea (OSA) in adults is considered medically necessary for patients who meet either of the following criteria on polysomnography:
   (a) Apnea Hypopnea Index (AHI) or a respiratory disturbance index (RDI) greater than or equal to 15 events per hour;
   OR
   (b) AHI (or RDI) greater than or equal to 5, and less than 15 events per hour with documentation demonstrating any of the following symptoms:
      (i) Excessive daytime sleepiness, as documented by either a score of greater than 10 on the Epworth Sleepiness scale or inappropriate daytime napping (e.g., during driving, conversation or eating) or sleepiness that interferes with daily-activities; or
      (ii) Impaired cognition or mood disorders; or
      (iii) Hypertension; or
      (iv) Ischemic heart disease or history of stroke; or
      (v) Cardiac arrhythmias, or
      (vi) Pulmonary hypertension.

2. **BI-LEVEL CPAP is indicated in the following conditions:**
BI-LEVEL CPAP is a device used mainly for severe cases of OSA.
Bi-level CPAP (with IPAP 4-22 cm water and EPAP 4-22 cm water)
   (a) When CPAP pressure requirement is greater than 16 cm
   (b) Oral leaks become uncontrollable at sub-therapeutic pressure after trying humidifier, chin strap & positive pressure therapy.
   (c) Pressure of central apneas due to too high pressures.
(d) When patient cannot tolerate CPAP after ensuring the problem is not due to oral leaks, dryness, nasal congestion, interface problem or claustrophobia.
(e) Patients with persistent hypoxia and / or hypercapnia after treatment with CPAP.

3. **BI-LEVEL Ventilatory support system is indicated in the following conditions:**
   
   Bi-level CPAP (with IPAP 4-30 cm water and EPAP 4-30 cm water)
   
   (a) **Restrictive Thoracic Disease** : (e.g. sequelae of polio, spinal cord injury, neuropathies, myopathies and dystrophies, amyotrophic lateral sclerosis, chest wall deformities and kyphoscoliosis, post thoracoplasty for TB) with symptoms (such as fatigue, dyspnea, morning headaches etc) and one of the following: (a) PaCO2 > 45 mmHg on room air or PaCO2 > 52 mmHg, done while awake and breathing the patient’s usual FiO2, (b) sleep oximetry demonstrating oxygen saturation ≤ 88% for at least 5 consecutive minutes done while breathing the patient’s usual FiO2; (c) for progressive neuromuscular disease (only) maximal inspiratory pressure is <60 cm H2O or forced vital capacity is < 50% predicted AND chronic obstructive pulmonary disease does not contribute significantly to the patient’s pulmonary limitation.

   (b) **Chronic Obstructive Pulmonary Disease (COPD)** (e.g. chronic bronchitis, emphysema, bronchiectasis) with symptoms (such as fatigue, dyspnea, morning headache etc.) and one of the following : (a) PaCO2 > 55 mmHg while awake and breathing patient’s usual FiO2 of 50-54 mmHg and nocturnal desaturation of spO2 ≤ 88% for 5 continuous minutes while receiving oxygen therapy ≥ 2 LpM; (c) PaCO2 of 50-54 mmHg and hospitalization related to recurrent (> 2 in a 12 month period) episodes of hypercapnic respiratory failure; optimal management with bronchodilators, oxygen when indicated must have been ensured; obstructive sleep apnea must have been excluded by polysomnography and there should preferably be an evidence of sustained hypoventilation as shown by prolonged episodes of desaturation during sleep.

   (c) **Nocturnal hypoventilation** from additional disorders (alveolar hypoventilation: central alveolar hypoventilation: central alveolar hypoventilation, idiopathic central sleep apnea, obesity hypoventilation syndrome, Cheyne-Stokes respiration, obstructive sleep apnea combined with COPD and pulmonary hypertension or CHF i.e. overlap syndrome, radiation fibrosis or occupational exposure disease; NPSG criteria for OSA not responsive to CPAP include (i) PSG criteria for mixed sleep apnea; not responsive to CPAP therapy (ii) other forms of nocturnal hypoventilation.

4. **Indications for humidification**

   (a) Positive Airway Pressure more than 12 cm water

   (b) Recurrent and intractable nasal stuffiness and blockage

   (c) Severe dryness of throat
(h) These indications are to be primarily thought of as palliative care. The patient should be willing to use for 16-18 hr per day. The decision to prescribe should be taken only after stabilization of medical treatment for 6-8 wks after acute exacerbation.

CONTRA-INDICATIONS TO OXYGEN PRESCRIPTION
(a) Dyspnoea in COPD with PaO2 > 60mmHg.
(b) Current tobacco smokers.
(c) Patients who have not received adequate therapy of other kinds.
(d) Patients who are not motivated to use oxygen therapy according to prescription.
(e) Patients who have cognitive impairment that prevent them from managing their own oxygen therapy appropriately and safely, or where a carer can not assist.
CERTIFICATE OF MEDICAL NECESSITY FOR PRESCRIPTION OF CONTINUOUS POSITIVE AIRWAY PRESSURE (CPAP) / BILEVEL CONTINUOUS POSITIVE AIRWAY PRESSURE (BI-LEVEL CPAP) / BI-LEVEL VENTILATORY SUPPORT SYSTEM / OXYGEN CONCENTRATORS

(To be filled by the treating physician)

1. OPD Regn No .............................................. date ......................

2. ECHS Card No ..............................................

Name of patient .............................................. Age ....... Relationship with ESM ..........

ESM Service No .............................................. Rank ................. Name ..............................................

Tele No .....................................................

3. (a) Brief history and physical findings

(b) Co-morbidity (if any)

(c) Whether accompanied by symptoms of

Excessive daytime sleepiness: Yes/No

Snoring: Yes/No

Impaired cognition: Yes/No

Documented cardiovascular disease like hypertension, ischemic heart disease or Stroke (specify if Yes) Yes/No.

4. Laboratory data (specify date against each parameter):

<table>
<thead>
<tr>
<th>Date</th>
<th>1</th>
<th>2</th>
<th>3</th>
</tr>
</thead>
<tbody>
<tr>
<td>Haematocrit</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>ECG</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Blood Sugar</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Lipid Profile</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Arterial Blood gases</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>pH</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>paO2</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>paCO2</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>HCO3 a</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>-------</td>
<td>---</td>
<td></td>
<td></td>
</tr>
<tr>
<td>HCO3 s</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>BE</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>O2 sat</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>X-ray Chest</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Echocardiography</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pulmonary function tests</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Thyroid function tests</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Ear, nose &amp; throat examination</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Others (specify)</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

5. Diagnostic nocturnal polysomnography (NPSG) data:
   
   (a) Date of sleep study
   (b) Address of sleep-laboratory /facility
   (c) Duration of diagnostic NPSG study (in hours)
   (d) Parameters studied during polysomnography

   Electro encephalogram        Yes/No
   Electrooculogram             Yes/No
   Electromyogram               Yes/No
   Oro nasal airflow            Yes/No
   Chest & abdominal wall effort Yes/No
   Body position                Yes/No
   Snore microphone             Yes/No
   Electro-cardiogram           Yes/No
   Oxyhaemoglobin saturation    Yes/No

   (e) Average number of obstructive per hour of recorded sleep (in case of standard as well as split NPSG)

      (i) Obstructive apnoea
      (ii) Hypopnea
(iii) Flow limitation.
(iv) RERA
(v) Sustained hype ventilation
(f) Respiratory Distress index (RDI)

Only whole night polysomnography (Level-1) including channels for sleep, breathing, pulse oxymetry, leg EMG, ECG, snoring will be accepted for consideration of BI-LEVEL CPAP/BI-LEVEL ventilatory support system

6. Date of BIPAP/ CPAP titration study

7. (a) BIPAP settings:
   Inspiratory pressure (IPAP)
   Expiratory pressure (EPAP)
   Backup Rate (if necessary)
   Supplemental oxygen (flow rate or FiO2)

(b) CPAP pressure (in cm H2O) prescribed:
(c) Supplemental oxygen (flow rate or FiO2)
(d) Humidification required Yes/ No

8. Final Diagnosis

9. Recommended: Oxygen Concentrator/ CPAP/ BI-LEVEL CPAP / BI-LEVEL ventilatory support system with/ without Humidifier

I certify that the medical necessity information is true, accurate and complete to the best of my knowledge. I have carefully gone through the note for prescribers before filling up this Proforma.

Date: ___________________________ (Full Name, signature & address of physician)

RECOMMENDATIONS

Recommended/ Not recommended

Senior Adviser

Consultant