CERTIFICATE OF MEDICAL NECESSITY TO BE ISSUED TO CGHS BENEFICIAREIS BEING PRESCRIBED BILEVEL CONTINUOUS POSITIVE AIRWAY PRESSURE (BI-LEVEL CPAP) / BI-LEVEL VENTILATORY SUPPORT SYSTEM

(To be filled by the treating physician)

Certification Type - *Initial/Revised*

1. Patient Name:

2. Age of Patient:

3. Physician Name:

4. Address of Physician:

5. Telephone No. of Physician:

6. (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

7. Laboratory Data (Specify date against each parameter)

Hematocrit:

ECG:

Blood Sugar (wherever necessary):

Lipid Profile (wherever necessary):

Arterial blood gases	1	2	3
Date			
pH			
paO_2			
$PaCO_2$			
HCO_3 a			
HCO_3 s			
BE			
O_2 sat			

(Note: The Arterial blood gas values should include those during chronic, stable state (atleast 3 months after an acute exacerbation) of the disease e.g. in a case of COPD, the ABG value during acute exacerbation generally demonstrates moderate to severe hypercapnia which may normalize during stable state and therefore may not be an indication for long term NIPPV)

X-ray Chest:

Echocardiography (wherever necessary):

Pulmonary function tests:

Thyroid function tests:

Ear, nose & throat examination:

Others (specify):

8. Diagnostic nocturnal polysomnography (NPSG) data: Only whole night polysomnography (Level-1) including channels for sleep, breathing, pulse oximetry, leg EMG, ECG, snoring will be accepted for consideration of BI-LEVEL CPAP/BI-LEVEL ventilatory support system

(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
- Electro-oculogram Yes/No
- Electro-myogram 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
- Oxyhemoglobin saturation Yes/No

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

(I) Obstructive apnoea*

(ii) Hypopnea**

(iii) Flow limitations***

(iv) RERA

(f) Respiratory Distress Index (RDI)****

9. Date of CPAP titration study:

10. CPAP pressure (in cm H_2O) prescribed (to abolish obstructive apnoeas,hypopneas, RERAs and snoring in all sleep positions and sleep stages):

11. Supplemental oxygen (flow rate of FiO2):

12. Final Diagnosis:

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)

Note for prescribers (For diagnostic as well as for titration):

Only whole night manually validated Level-1 polysomnography including channels for sleep, breathing, pulse oximetry, leg EMG, ECG, snoring & CPAP titration will be accepted for consideration of CPAP/ BiPAP. 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.

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

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

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

***** RERA (respiratory effort-related arousal)** is defined as an event characterized by increasing respiratory effort for ≥10 seconds leading to arousal from sleep but which does not fulfill the criteria for hypopnoea or apnoea. 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.

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 apnoea/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.

Split-Night Study NPSG: Patients with an 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 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.

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 associated 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, an 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.

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)

I. When CPAP pressure requirement is greater than 16cm

II. Oral leaks become uncontrollable at sub-therapeutic pressure after trying humidifier, chin strap & positive pressure therapy.

III. Pressure of central apneas due to too high pressures

IV. When patient cannot tolerate CPAP after ensuring the problem is not due to oral leaks, dryness, nasal congestion, interface problem or claustrophobia.

V. Patients with persistent hypoxia and/or hypercapnia after treatment with CPAP

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)

(I). 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, dyspnoea, morning headaches etc.) and one of the following: (a) $PaCO_2 \geq 45$mmHg on room air or $PaCO_2 \geq 52$ mmHg, done while awake and breathing the patient's usual FiO_2, (b) sleep oximetry demonstrating oxygen saturation $\leq$ 88% for at least than 5 consecutive minutes done while breathing the patient's usual FiO_2; (c) for progressive neuromuscular disease (only) maximal inspiratory pressure is < 60 cm H_2O or forced vital capacity is < 50% predicted AND chronic obstructive pulmonary disease does not contribute significantly to the patient's pulmonary limitation.

(II) Chronic Obstructive Pulmonary Disease (COPD): (e.g. chronic bronchitis, emphysema, bronchiectasis) with symptoms (such as fatigue, dyspnoea, morning headache etc.) and one of the following: (a) $PaCO_2 > 55$ mmHg while awake and breathing patient's usual FiO_2 (b) $PaCO_2$ of 50-54 mmHg and nocturnal desaturation of $spO_2 \leq 88\%$ for 5 continuous minutes while receiving oxygen therapy $\geq$ 2 LPM; (c) $PaCO_2$ of 50-54 mmHg and hospitalization related to recurrent ($\geq$ 2 in a 12 month period) episodes of hypercapneic respiratory failure; optimal management with bronchodilators, oxygen when indicated must have been ensured; obstructive sleep apnoea must have been excluded by polysomnography and there should preferably be an evidence of sustained hypo-ventilation as shown by prolonged episodes of desaturation during sleep.

(III) Nocturnal hypo-ventilation from additional disorders (alveolar hypo-ventilation: central alveolar hypo-ventilation, idiopathic central sleep apnoea, obesity hypo-ventilation syndrome, Cheyne-Strokes respiration obstructive sleep apnoea combined with COPD and pulmonary hypertension of CHF i.e. overlap syndrome, radiation fibrosis or occupational exposure diseases; NPSG criteria for OSA not responsive to CPAP include (i) PSG criteria for mixed sleep apnoea not

responsive to CPAP therapy (ii) central sleep apnoea; (iii) other forms of nocturnal hypo-ventilation.

Indications for humidification

(iv) Positive Airway Pressure more than 12 cm water
(v) Recurrent and intractable nasal stuffiness and blockage
(vi) Severe dryness of throat