CERTIFICATE OF MEDICAL NECESSITY TO BE ISSUED TO CGHS BENEFICIARIES BEING PRESCRIBED CONTINUOUS POSITIVE AIRWAY PRESSURE (CPAP) DEVICE ***(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) e.g. COPD, diabetes mellitus etc.

(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

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ECG

Blood Sugar

Lipid Profile

Arterial blood gases:

	1	2	3
Date			
pH			
paO_2			
$paCO_2$			
HCO_3 a			
HCO_3 s			
BE			
O_2 sat			

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-I) including channels for sleep, breathing, pulse oxymetry, leg EMG, ECG, snoring will be accepted for consideration of CPAP/BiPAP

(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 or FiO_2):

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)**

For draft

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

Only whole night manually validated Level-1 polysomnography including channels for sleep, breathing, pulse oxymetry, 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 nonsinusoidal 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 any flow limitation event associated with 3% desaturation or associated with an AASM arousal.

*** **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 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 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.

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:

1. Apnea Hypopnea Index (AHI) or a respiratory disturbance index (RDI) greater than or equal to 15 events per hour; OR
2. AHI (or RDI) greater than or equal to 5, and less than 15 events per hour with documentation demonstrating any of the following symptoms:
    - 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
    - Impaired cognition or mood disorders; or
    - Hypertension; or
    - Ischemic heart disease or history of stroke; or
    - Cardiac arrhythmias, or
    - Pulmonary hypertension.

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 as apneic or hypopneic episodes because of the absence of their defining air flow changes and/or levels of oxygen desaturation.*

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