सत्यमेव जयते

No. S. 11011/4/2014-CGHS(P)
Government of India
Ministry of Health & Family Welfare
CGHS (P)

Nirman Bhavan, New Delhi
Dated the 5th March, 2014

OFFICE MEMORANDUM

Sub. : Provision of CPAP/BIPAP/Oxygen concentrator, in respect of CGHS beneficiaries for domiciliary use – Grant of permission / ex-post facto approval and reimbursement of the cost of the same – reg.

The undersigned is directed to state that the Ministry of Health & Family Welfare has been receiving requests from CGHS beneficiaries for permission to purchase Oxygen Concentrator/BIPAP/CPAP etc. as prescribed the specialist doctor and claim reimbursement of the cost of above said machines for the second time and also for reimbursement of expenditure incurred on maintenance of these machines which were provided earlier for domiciliary use by CGHS. These machines were allowed to be purchased once in life-time with the condition that the responsibility and maintenance of the said machine would like with the beneficiary as per the Office Memorandum no. 24-26/96/R&H/CGHS/Part I/CGHS(P) dated 26th June, 2001 issued by this Department on the above subject.

2. The issue has been considered by this Ministry in consultation with a Committee of Specialists constituted for this purpose and the following guidelines have been framed for considering requests for permission to purchase Oxygen Concentrator/BIPAP/CPAP etc. by CGHS beneficiaries and regulating reimbursement of cost of such machines to the CGHS cardholders.

i) Request of the beneficiaries should be accompanied with the relevant Proforma prescribed by CGHS for the machine, duly filled up by the treating physician (specimen copy of proformae attached). The treating physician should carefully read the laid down guidelines before filling up the respective columns of the Proforma Actual value of all the parameters mentioned in Proforma should invariably be entered and complete basic investigation reports must be attached.

A. Arterial blood gas report taken while the patient is in stable condition and is breathing room air (in case of oxygen concentrator and bi-level ventilator supplier system).

B. Detailed in lab-level-1 polysomnography report (including all the tracings and tables) in case of recommendation for CPAP and Bi-Level CPAP.

ii) As these machines are lifesaving devices and have a maximum life of five years, these will be allowed to be replaced again after a period of five years subject to a certificate by the service engineer regarding the on-serviceability/condemnation/ of the earlier machine provided by CGHS.

iii) **The beneficiary has also to submit an undertaking to the effect that the has not claimed reimbursement of the cost of the machine in the last five years (copy of format for the affidavit and the undertaking is enclosed).**

iv) **The machine is to be deposited back with the CMO in charge of the CGHS Wellness Center concerned after the utility of the same is over and the machine will not be re-issued to another patient by CGHS CMOs incharge in Delhi and NCR will deposit the used machines to CGHS Medical Stores Depot, Gole Market, New Delhi. CMOs in-charge in other CGHS cities will deposit these used machines in the Office of Additional Director of the CGHS city and obtain acknowledgement. The concerned offices will maintain complete records of such machines.**

v) **Individual requests for permission/ex-post facto approval shall be considered by the screening committee consisting of :-**

Additional Director, CGHS (HQ)/City AD Concerned	**Chairman**
Two specialists pertaining to Respiratory/Pulmonary diseases/Medicines.	**Member**

vi) **The maximum ceiling limit for reimbursement will be as following :-**

a. Oxygen Concentrator	**Rs.60,000/-**
b. CPAP	**Rs.50,000/-**
c. Bi-level CPAP	**Rs.80,000/-**
d. B9-level Ventilatory system	**Rs.1,20,000/-**

The above ceiling limits include cost of maintenance with spare parts for a period of five years. No request for reimbursement of cost of maintenance/parts will be entertained.

vii) **Request for replacement of machine after completion of five years will need to be advised and processed in the same manner as for the first machine.**

viii) **Request for permission/ex-post facto approval of these machines, complete in all respect as mentioned above may be sent to :-**

a. **Additional Director (HQ), CGHS Delhi/Additional Director of City concerned in respect of serving beneficiaries having CGHS card registered in Delhi/outside as the case may be.**

b. **CGHS Wellness Centers in respect of pensioner beneficiaries.**

3. This Office Memorandum supersedes all earlier instructions issued on this subject. These instructions shall take effect from the date of issue of this Office Memorandum i.e. all requests under this OM should have advice for these machines subsequent to the issue of this OM.

4. This issue with concurrence of IFD vide CD No. C-1033, dated 06.09.2013.

Encl : As above.

(V.P. Singh)
Deputy Secretary to the Government of India
Tel. :- 2306 1831

To,

1. All Ministries/Departments, Government of India.
2. Director, CGHS, Nirman Bhawan, New Delhi.
3. Addl. DDG(HQ), CGHS, MoHFW, Nirman Bhawan, New Delhi.
4. AD(Hq), CGHS, Bikaner House, New Delhi
5. All Additional Directors/Joint Directors of CGHS cities outside Delhi.
6. Additional Director (SZ)/(CZ)/(EZ)/(NZ), CGHS, New Delhi.
7. JD(HQ)/JD(Gr.)/JD (R&H), CGHS, Delhi.
8. CGHS-I,/II/III/IV, Dte. General of CGHS Nirman Bhavan, New Delhi.
9. Estt. I/Estt.II/Estt. IV/MS Sections of MoHFW,Nirman Bhawan, New Delhi.
10. Admn. I/Admn. II Sections of Dte. GHS
11. Rajya Sabha/Lok Sabha Secretariat.
12. Registrar, Supreme Court of India.
13. U.P.S.C. Dholpur House, Shahjahan Road, New Delhi.
14. Integrated Finance Division, MoHFW, Nirman Bhavan, New Delhi.
15. PPS to Secretary (H&FW)/Secretary (AYUSH)/Secretary (HR)/ Secretary(AIDS Control), Ministry of Health & Family Welfare.
16. PPS to DGHS/AS&DG(CGHS)/AS&MD, NRHM
17. Office of the Comptroller & Auditor General of India, Bahadur Shah Zafar Marg, New Delhi.
18. Deputy Secretary (Civil Service News), Department of Personnel & Training, 5th Floor, Sardar Patel Bhawan, New Delhi.
19. Swamy Publishers (P)Ltd., P.B.No. 2468, R.K. Puram, Chennai 600028.
20. Shri Umraomal Purohit, Secretary, Staff Side, 13-C, Ferozshah Road, New Delhi.
21. All Staff Side Members of National Council (JCM) (as per list attached).
22. All Offices/Sections/Deks in the Ministry.
23. ED(H)/Planning, Railway Board, Ministry of Railways, Rail Bhavan, Rafi Marg, New Delhi 110 001.
24. Central Organisation, ECHS, Department of Ex-serviceman welfare, Ministry of Defence, New Delhi.
25. Chairman Employees State Insurance Corporation, Ministry of Labour & Employment Panchdeep Bhavan, C.I.G. Marg, New Delhi 110 002.
26. UTI-ITSL 153/1, First Floor, Old Madras Road, Ulsoor, Bengaluru 560008.
27. Sr. Technical Director NIC, MOHFW Nirman Bhawan, New Delhi with the request to upload this OM on the CGHS website.
28. Guard File.

Lipid Profile (wherever necessary)

Arterial blood gases.

Date

pH

paO_2

HCO_3 a

HCO_3 s

BE

O_Z 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 normalise 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 and throat examination

Others (specify).

8. Diagnostic nocturnal polysomnography (NPSG) data: Only whole night polysomnography (Level-1) including channels for sleep, breating, pulse oxymetry, 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-encephlogram	**Yes/No**
Electro-oculogram	**Yes/No**
Electro-myogram	**Yes/No**
Oro-nasal airflow	**Yes/No**

CERTIFICATE OF MEDICAL NECESSITY TO BE ISSUED TO CGHS BENEFICIARIES 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

Hypetension, ischemic heart disease or

Stroke (specify if Yes). : Yes/No

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

Hematocrit

ECG

Blood Sugar (wherever necessary).

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

(v) Sustained hypoventilation

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

9. Date of BIPAP titration study.

10. BIPAP settings : Inspiratory pressure (IPAP) Expiratory pressure (EPAP) Backup Rate (if necessary) Supplemental oxygen (flow rate or FiO_2)

11. Final Diagnosis

12. Recommended : BI-LEVEL CPAP/BI-LEVEL ventilatory support system

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 and 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 oxymetry, leg EMG, ECG, snoring & BI-LEVEL titration will be accepted for consideration of BI-LEVEL CPAP/BI-LEVEL ventilatory 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.

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

***** 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 characterised by increasing respiratory effort for ≥ 10 seconds leading to arousal from sleep but which does not fulfill the criteria for hypopnoca 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.**

Hypoventilation As mentioned in the note for prescribers.

****** RDI (respiratory distress index) is defined as the number of obstructive apnoeas, 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).**

Upper airway resistance syndrome (UARS) : Is an abnormal breathing pattern during sleep that is associated with isolated daytime sleepiness not explained by any othe cause, including the obstructive sleepapnoea/

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

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, legal EMG, ECG, snoring and 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 shoring (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 diagnosti NPSG receive a split-night study NPSG, of which the final portion of the NPSG is used to titrateCPAP,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 recognition 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 apnei or hypopneic episodes because of the absence of their defining air flow changes and/or levels of oxygen desaturation.

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

Home oxygen therapy is the home administration of oxygen at concentrations greater than the ambient air with the intention of treating or preventing the symptoms and manifestations of hypoxic or non-hypoxic medical conditions that are known to clinically improve with oxygen.

Clinical Indications

Home oxygen therapy is considered medically necessary in the following circumstances.

1. **Chronic hypoxia (generally long term use). The conditions with which this may be associated include, but are not limited to :**

    - **Chronic obstructive pulmonary disease.**
    - **Diffuse intestitial lung disease.**
    - **Bronchiectasis.**
    - **Widespread pulmonary neoplasm.**
    - **Pulmonary hypertension.**
    - **Recurring congestive heart failure due to chronic or pulmonale.**

The following laboratory values, obtained while breathing ambient air, will be presumptive evidence for hypoxia :

Adults :

Arterial partial pressure of oxygen (PaO2) less than or equal to 55mmHg or arterial oxygen saturation (SaO2) less than or equal to 88%.

PaO2 levels between 56 and 59 or SaO2 89% in the presence of pulmonary hypertension, cor pulmonale, edema secondary to right heart failure, or erythrocytosis with hematicrit greater than 55%.

Note :

1. **Patients who desaturte to an SaO2 less than or equal to 88% only during exercise and who demonstrate improvement in both the hypoxia and dyspnea and/or exercise capacity when using O2 are candidates for supplemental O2 during exercise only.**

2. **Patients who desaturae only during sleep to an SaO2 of less than or equal to 88% for more than 30% of the night or with evidence of otherwise unexplained pulmonary hypertension, cor pulmonale, adema secondary to right heart failure or erythrocytosis with**

hematocrit greater than 55% and in whom obstructive sleep apnea (OSA) and other nocturnal apnea or hypoventilation syndromes have been ruled out of, if OSA present have persistent desaturation despite correction of AHI (RDI) by CPAP, are candidates for nocturnal O2.

Infants and children :

Arterial partial pressure of oxygen (PaO2) less than or equal to 60 mmHg or arterial oxygen saturation (SaO2) less than or equal to 92%.

Note: Portable oxygen systems are considered medically necessary only when needed to complement the medical needs of an individual who requires a stationary system.