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भारत सरकार
GOVERNMENT OF INDIA

परमाणु ऊर्जा विभाग

DEPARTMENT OF ATOMIC ENERGY

औ. सं. एवं क. अनुभाग
IR&W SECTION

अणुशक्ति भवन

Anushakti Bhavan,

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कार्यालय ज्ञापन OFFICE MEMORANDUM

**विषय : सीएचएसएस लाभार्थियों के आवासीय उपयोग हेतु सीपीएपी/
बीआईपीएपी/ऑक्सीजन कंसंट्रेटर के प्रावधान के संबंध में।**

**Sub : Provision of CPAP/BIPAP/Oxygen concentrator in
respect of CHSS beneficiaries for domiciliary use – reg.**

इस विभाग में सीजीएसएस नियमों और अंतरिक्ष विभाग के सीएचएसएस के अनुसार सीएचएसएस लाभार्थियों के आवासीय उपयोग हेतु सीपीएपी/बीआईपीएपी/ऑक्सीजन कंसंट्रेटर के प्रावधान के लिए संदर्भ प्राप्त हुए हैं।

Reference has been received in the Department for provision of CPAP, BIPAP, Oxygen Concentrator etc. for domiciliary use to CHSS beneficiaries on line with CGHS Rules and DOS CHSS.

2. इस विभाग में और विभाग की सीएचएसएस समीक्षा समिति द्वारा भी इस विषय की जाँच की गई है। इस समिति की सिफारिशों के आधार पर और सीजीएसएस के तहत लाभार्थियों के लिए स्वास्थ्य एवं परिवार कल्याण मंत्रालय द्वारा विहित दिशा-निर्देशों और मानदंडों पर विचार करके विभाग सीएचएसएस लाभार्थियों द्वारा ऑक्सीजन कंसंट्रेटर/बीआईपीएपी/सीपीएपी आदि की खरीद करने और निम्नलिखित शर्तों को पूरा करने पर ऐसी मशीनों की कीमत की प्रतिपूर्ति करने हेतु अनुमति देने के लिए सहमत हुआ है।

The matter has been examined in the Department and also by the CHSS Review Committee in the Department. Based on the recommendations of the Committee and considering the guidelines/criteria provided by the Ministry of Health and Family Welfare for beneficiaries under CGHS, the Department has agreed to grant permission to purchase

Oxygen Concentrator/BIPAP/CPAP, etc. by CHSS beneficiaries and reimburse the cost of such machines subject to fulfilling the following:

- (i) खरीद हेतु अनुमति केवल विभागीय स्तर पर दी जाएगी। संबंधित केंद्र और यूनिट द्वारा शर्तों को पूरा करने वाले मामलों पर विचार और अनुमोदन हेतु पऊवि को सिफारिश किए जाएं;

Permission for purchase to be given only at the Department level. Cases fulfilling the conditions may be recommended by the respective Centre/Unit to DAE for consideration and approval;

- (ii) लाभार्थी का अनुरोध इस कार्यालय ज्ञापन के साथ जुड़े निर्धारित प्रपत्र क्र. I/II/III (प्रतियाँ संलग्न) में उपचार करने वाले डॉक्टर की सिफारिशों सहित संबंधित केंद्र/यूनिट में किया जाएगा। उपचार करने वाला डॉक्टर प्रपत्र के संबंधित कॉलम भरने से पहले निर्धारित दिशा-निदेशों को सावधानीपूर्वक पढ़ेगा। प्रपत्र में दर्शाये गए सभी पैरामीटरों की वास्तविक वैल्यू को अनिवार्य रूप से प्रविष्ट करेगा और बेसिक जाँच रिपोर्ट अवश्य संलग्न की जाएगी:

The request of the beneficiary should be made to the respective Centre/Unit along with the recommendations of the treating physician in the prescribed Form No. I/II/III to this OM (copies enclosed). The treating physician should carefully read the laid down guidelines before filling up the respective columns of the Form. Actual value of all the parameters mentioned in Form should invariably be entered and complete basic investigation reports must be attached:

- a. मरीज की हालत स्थिर होने और रूम एअर का श्वसन लेते समय ली गयी आर्टेरियल ब्लड गैस रिपोर्ट (ऑक्सीजन कंसंट्रेटर एवं बाई-लेवल वेंटिलेटरी सप्लायर सिस्टम)

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. सीपीएपी एवं बाई-लेवल सीपीएपी की सिफारिश की हालत में डिटेल्ड इन-लैब लेवल-I पालीसोमनोग्राफी रिपोर्ट (सभी ट्रेसिंग एवं टेबल सहित)

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

- (iii) चूंकि ये मशीनें जीवन रक्षक उपस्कर होती हैं और इनकी अधिकतम लाइफ पाँच वर्ष है, इसलिए सीएचएसएस के तहत पूर्व में उपलब्ध करायी गयी मशीन की अनुपयुक्तता/अनुपयोगिता के संबंध में सर्विस इंजीनियर द्वारा सर्टिफिकेट की शर्त पर इन्हें बदला जा सकता है। इसे बदलने के लिए अनुमति देने हेतु पुरानी मशीन

को सिफारिश करने वाले केंद्र/यूनिट में जमा करना आवश्यक होगा। यदि पुरानी मशीन वापस नहीं की जाती है, तो मशीन बदलने के लिए किसी अनुरोध पर विचार नहीं किया जाएगा।

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 un-serviceability/condemnation of the earlier machine provided under CHSS. For approving a replacement, the old machine is required to be deposited back to the recommending Centre/Unit. If the old machine is not returned back, no request for replacement will be considered.

- (iv) लाभार्थी को इस संबंध में एक शपथ पत्र भी देना होगा कि उसने पिछले पाँच वर्षों में मशीन की प्रतिपूर्ति का दावा नहीं किया है। (शपथ पत्र के लिए फार्मेट की प्रति संलग्न है)

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

- (v) प्रतिपूर्ति के लिए अधिकतम निर्धारित सीमा नीचे दी गई है :

The maximum ceiling limit for reimbursement will be as following:

- | | |
|---|--------------------|
| a. ऑक्सीजन कंसंट्रेटर Oxygen Concentrator - | रु.Rs. 60,000/- |
| b. सीपीएपी CPAP | - रु.Rs. 50,000/- |
| c. बाई-लेवल सीपीएपी Bi-level CPAP | - रु.Rs. 80,000/- |
| d. बाई-लेवल वेंटिलेटरी सिस्टम Bi-level Ventilatory System | - रु.Rs.1,20,000/- |

उपर्युक्त अधिकतम निर्धारित सीमा में पाँच वर्षों की अवधि के लिए स्पेयर पार्ट्स सहित रखरखाव की कीमत शामिल है। रखरखाव/पार्ट की लागत की प्रतिपूर्ति के लिए कोई अनुरोध स्वीकार नहीं किया जाएगा।

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

- (vi) मशीन का विवरण जैसा कि मॉडल नं., मेक आदि जिसके लिए लागत की प्रतिपूर्ति अनुमोदित की गई है, की प्रविष्टि नामित हास्पिटल/डिस्पेंसरी या प्रशासन द्वारा आवश्यक अनुवर्ती कार्रवाई हेतु मेडिकल रिकार्ड/सर्विस रिकार्ड में की जाएगी।

Details of the machine such as its model no., make, etc., for which reimbursement of cost of has been approved, should be entered in the

medical record/service records for necessary follow-up by the designated hospital/dispensary or by the Administration.

3. इसे सक्षम प्राधिकारी के अनुमोदन से जारी किया जाता है।
This issues with the approval of competent authority.



(राकेश गर्ग Rakesh Garg)

निदेशक (आईआरएंडडब्ल्यू) Director (IR&W)

सभी सीएचएसएस नियंत्रण प्राधिकारी All CHSS Administering Authorities

शपथ पत्र AFFIDAVIT

(सीपीएपी/बाई-लेवल वेंटीलेटरी सिस्टम/ऑक्सीजन कंसंट्रेटर मशीन के लिए नोटरीयुक्त शपथ-पत्र)

(Notarized Affidavit for CPAP/Bi-level CPAP/Bi-level Ventilatory System/Oxygen Concentrator Machine)

मैं श्री/श्रीमती/कुमारी _____ पुत्र/पुत्री/पत्नी/पति _____ एक कार्यरत/पेंशनर सीएचएसएस लाभार्थी, सीएचएसएस सं. _____ निवासी _____ सीएचएसएस डिस्पेंसरी _____ से संबद्ध, सत्यनिष्ठा से यह वचन देता/देती हूँ और घोषणा करता/करती हूँ कि :

I Sh./Smt/Kum. _____ S/DW/H/o _____ a serving/pensioner CHSS beneficiary, CHSS No. _____ R/o _____ attached with the CHSS dispensary _____ do solemnly affirm and declare that :

डॉ. _____ अस्पताल _____ द्वारा दिनांक _____ को _____ के लिए सीपीएपी/बाई-लेवल वेंटीलेटरी सिस्टम/ऑक्सीजन कंसंट्रेटर मशीन की सलाह दी गयी है।

The CPAP/Bi-level CPAP/Bi-level Ventilatory System/Oxygen Concentrator machine has been advised by Dr. _____ Hospital _____ on dated _____ in respect of _____.

मैं यह शपथ लेता/लेती हूँ कि _____ से संबंध सीएचएसएस डिस्पेंसरी (जिससे मैं संबद्ध हूँ) को सीपीएपी/बाई-लेवल वेंटीलेटरी सिस्टम/ऑक्सीजन कंसंट्रेटर मशीन को उसकी उपयोगिता समाप्त हो जाने पर अच्छी अवस्था में वापस करूंगा/करूंगी।

I undertake to return CPAP/Bi-level CPAP/Bi-level Ventilatory System/Oxygen Concentrator machine in good condition to CHSS dispensary _____ (to which I am attached) after its utility is over.

इसके साथ ही, मशीन लेने के बाद किसी भी समय दुर्भाग्यवश मेरी मृत्यु होने की स्थिति में मशीन को उसे जारी करने वाली डिस्पेंसरी/अस्पताल को वापस करने की जिम्मेदारी मेरे निकटतम परिवार जन की होगी।

Further, in the unfortunate event of my death, anytime after acquiring the machine, it shall be the responsibility of my immediate family members to return the machine to the dispensary/hospital issuing the same.

मशीन के मेंटेनेंस और देखरेख की जिम्मेदारी मेरी होगी। मशीन के मेंटेनेंस और देखरेख पर यदि कोई खर्च आता है तो मैं उस पर हुए व्यय पर दावा नहीं करूंगा/करूंगी।

The responsibility for maintenance and upkeep of the machine will lie with me. I shall not claim expenditure incurred, if any on upkeep and maintenance of the machine.

में सीएचएसएस लाभार्थियों के लिए पऊवि द्वारा निर्धारित व्यय सीमा में दावा प्रस्तुत करूंगा/करूंगी और शेष राशि, यदि कोई हो तो, वह मेरे द्वारा वहन की जाएगी।

I will submit the claim at ceiling prescribed by DAE for its CHSS beneficiaries and the remaining amount, if any, will be borne by me.

मैंने एक पूरी स्लीप लैब रिपोर्ट/एबीजी रिपोर्ट और उपचार करने वाले विशेषज्ञ द्वारा विधिवत भरा हुआ प्रोफार्मा इसके साथ संलग्न करा है।

I have enclosed a complete sleep lab report/ABG report and proforma duly filled up by treating specialist.

में उपर्युक्त मशीन का _____ के उपचार के अतिरिक्त किसी अन्य प्रयोजन हेतु उपयोग नहीं करूंगा/करूंगी।

I shall not use the aforesaid machine for any other purpose except treatment of _____.

में, अधोहस्ताक्षरीकर्ता, यह घोषणा करता/करती हूँ कि मैंने पिछले पांच वर्षों में सरकारी खर्च पर कोई सीपीएपी/बाई-लेवल वेंटीलेटरी सिस्टम/आक्सीजन कंसट्रेटर मशीन नहीं खरीदी है:

I, the undersigned, do hereby declare that, I have not purchased any CPAP/Bi-level CPAP/Bi-level Ventilatory System/Oxygen Concentrator machine, in the past five years at Government expenses:

1. नाम Name :
2. सीएचएसएस सं. CHSS No. :
3. संबद्ध सीएचएसएस डिस्पेंसरी :
CHSS Dispensary to which attached
4. सीएचएसएस कार्ड की वैधता Validity of CHSS Card :
5. आवेदक का पता/मोबाइल :
Address of Applicant/Mobile

दिनांक Date:

आवेदक का हस्ताक्षर
Signature of the Applicant

HCO₃s

BE

O₂sat

(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 oxymetry, leg EMG, ECG, snoring will be accepted for consideration of BI-LEVEL CPAP/BI-LEVEL ventilator 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-cardiography | 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 CAP titration study
10. CPAP pressure (in cm H₂O) prescribed (to abolish obstructive apnoeas, hypopneas, RERAs and snoring in all sleep positions and sleep stages):
11. Supplemental oxygen (flow rate or 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 oxymetry, leg 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 >10s.

**** 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.

***** 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.

******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 a RDI of >40 events per hour during the first 2 hours of a diagnostic NPSG receive 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 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. Presence 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, dyspnea, morning headaches etc.) and one of the following: (a) $\text{PaCO}_2 \geq 45$ mmHg on room air or $\text{PaCO}_2 \geq 52$ mmHg, done while awake and breathing the patient's usual FiO_2 ; (b) sleep oximetry demonstrating oxygen saturation $\leq 88\%$ for at least 5 continuous 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, dyspnea, morning headache etc.) and one of the following: (a) $\text{PaCO}_2 > 55$ mmHg while awake and breathing patient's usual

FiO₂ (b)PaCO₂ 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 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 evidence of sustained hypoventilation as shown by prolonged episodes of desaturation during sleep.

- (III) Nocturnal hypoventilation from additional disorders (alveolar hypoventilation: central alveolar hypoventilation, idiopathic central sleep apnoea, obesity hypoventilation syndrome, Cheyne-Stokes respiration, obstructive sleep apnoea combined with COPD and pulmonary hypertension or 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 hypoventilation.

Indications for humidification

- (I) Positive Airway Pressure more than 12 cm water
- (II) Recurrent and intractable nasal stuffiness and blockage
- (III) Severe dryness of throat

Form-II to OM No. 7/3/2017/IR&W(Vo.-II)/2487 dated 21.2.2019

Certificate of Medical Necessity to be issued to CHSS Beneficiaries being prescribed Continuous Positive Airway Pressure (CPAP) Device

(To be filed 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

ECG

Blood sugar

Lipid Profile

Arterial blood gases:	1	2	3
Date			
pH			
paO ₂			
paCO ₂			
HCO _{3a}			
HCO _{3s}			
BE			
O ₂ sat			

X-ray Chest

Echocardiography (wherever necessary)

Pulmonary function tests

Thyroid function test

Ear, nose & throat examination

Others (specify)

8. Diagnostic nocturnal polysomnography (NPSG) date: Only whole night polysomnography (Level-1) 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 H₂O) prescribed (to abolish obstructive apnoeas, hypopneas, REPAs and snoring in all sleep positions and sleep stages):

11. Supplemental oxygen (flow rate or 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 oxymetry, leg EMG, ECG, snoring & CPAP titration will be accepted for consideration of CPAP/BiPAP. Screening studies 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

****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.

*****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.

******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 arousal 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 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 a clinical observations, such as the occurrence of obstructive respiratory events with a prolonged duration or 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 arousal (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.

Form-III to OM No. 7/3/2017/IR&W(Vo.-II)/2487 dated 21.2.2019

Certificate of Medical Necessity to be issued to CHSS Beneficiaries being prescribed long term Oxygen Therapy/Oxygen Concentrator

(To be filled by the treating physician)

Certificate 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

X-ray Chest

Echocardiography (wherever necessary)

Pulmonary function 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 (at least 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 hypoxemia and hypersapnia which may normalise during stable state and therefore may not be an indication for long term oxygen therapy)

Others (specify)

8. Final Diagnosis

9. Recommended : Oxygen concentrator/portable oxygen cylinder/compressed oxygen cylinders)

(a) Flowrate

(b) Nasal prongs/Cannula

(c) Nasal mask

(d) Number of hours per day

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, Signatgure & Address of Physician)

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 interstitial lung disease
 - Bronchiectasis
 - Widespread pulmonary neoplasm
 - Pulmonary hypertension
 - Recurring congestive heart failure due to chronic cor 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 hematocrit greater than 55%.

Note:

1. Patients who desaturate 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 desaturate only during sleep to an SaO₂ of less than or equal to 88% for more than 30% of the night or with evidence or otherwise unexplained pulmonary hypertension, cor pulmonale, edema 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 or, 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 60mmHg 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.