DRAFT

Use of this template is voluntary / optional

Respiratory Assist Device

Face to Face (F2F) Encounter Template Guidance

Purpose

This template is designed to assist a clinician in documenting a face-to-face (F2F) encounter for a Respiratory Assist Device (RAD) and accessories to meet requirements for Medicare eligibility and coverage. The clinician can keep the completed template on file within the patient's medical record or it can be used to develop an F2F encounter note for use with the system containing the patient's electronic medical record.

Patient eligibility for coverage of RAD therapy under Medicare

Eligibility for coverage of RAD therapy equipment and accessories under Medicare requires a physician or qualified Non-Physician Practitioner (NPP)[1] to establish that coverage criteria are met. This helps to ensure the RAD and accessories provided are consistent with the physician's prescription and supported in the patient's medical record.

A Face-to-Face (F2F) encounter is required by Medicare for the following RAD devices:

> **E0470** - RESPIRATORY ASSIST DEVICE, BI-LEVEL PRESSURE CAPABILITY, WITHOUT BACKUP RATE FEATURE, USED WITH NONINVASIVE INTERFACE, E.G., NASAL OR FACIAL MASK (INTERMITTENT ASSIST DEVICE WITH CONTINUOUS POSITIVE AIRWAY PRESSURE DEVICE)
>
> **E0471** - RESPIRATORY ASSIST DEVICE, BI-LEVEL PRESSURE CAPABILITY, WITH BACK-UP RATE FEATURE, USED WITH NONINVASIVE INTERFACE, E.G., NASAL OR FACIAL MASK (INTERMITTENT ASSIST DEVICE WITH CONTINUOUS POSITIVE AIRWAY PRESSURE DEVICE)
>
> **NOTE**: RAD accessories do not require a F2F encounter, but do require a Detailed Written Order (DWO}.

The F2F Encounter must be completed within a 6-month timeframe prior to completion of the Written Order Prior to Delivery (WOPD) that starts RAD therapy for the treatment of a clinical condition supported by the patient's diagnosis. (See Appendix A.)

[1] *A Medicare allowed NPP is defined as a nurse practitioner, clinical nurse specialist, or physician assistant (as those terms are defined in section 1861 (aa) (5) of the Social Security Act) who is working in accordance with State law.

Indications for use of a RAD is divided into four categories:

- Restrictive thoracic disorders, (i.e., progressive neuromuscular disorders or severe thoracic cage abnormalities);
- Severe chronic obstructive pulmonary disease (COPD); use of a RAD in COPD patients requires,
    - A facility-based polysomnogram to rule out obstructive sleep apnea in order to initiate Medicare coverage,
    - A prerequisite trial of noninvasive ventilation without a backup rate, and
    - Treatment with continuous positive airway pressure devices.
- Central sleep apnea, i.e., apnea not due to airway obstruction;
- Hypoventilation; and
- Obstructive sleep apnea (OSA).

See Appendices A&B for further guidance on indication for use and coverage.

Initial coverage -- first three (3) months of therapy

The medical record must document symptoms characteristic of sleep-associated hypoventilation, e.g.:

- Daytime hypersomnolence;
- Excessive fatigue;
- Morning headache;
- Cognitive dysfunction;
- Dyspnea, etc.; and
- Beneficiary has one (1) of the disorders listed above and meets all coverage criteria for that disorder as listed below.

Continued coverage (beyond the first three months of therapy) - E0470 or E0471

Medical record documentation that has a signed and dated statement that the beneficiary was re-evaluated on/after the 61st day of therapy demonstrating:

- Progress of relevant symptoms; and
- Beneficiary usage of the device (average 4 hours per 24 hours)

Beneficiaries entering Medicare

There must be documentation of the following:

- A qualifying test confirming that the beneficiary had testing prior to Fee-for-Service (FFS) Medicare enrollment, that meets the current coverage criteria in effect at the time that the beneficiary seeks Medicare coverage of a replacement device and/or accessory; and
- There must be an F2F clinical evaluation following enrollment in FFS Medicare that confirms all of the following:
    - The beneficiary has the qualifying medical condition for the applicable scenario; and
    - Testing performed, date of the testing used for qualification and results; and
    - The beneficiary continues to use the device; and
    - The beneficiary is benefiting from the treatment.

Other guidance

Completing the RAD order template does not guarantee eligibility and coverage but does provide an area within the patient's medical file that is readily identifiable and available in support of RAD therapy equipment and accessories ordered and billed to Medicare. This template may be used with the Respiratory Assist Device Laboratory Test Results Template and Respiratory Assist Device Order Template.

Who can complete the F2F encounter template?

A physician or allowed NPP who performs an F2F encounter:

Note: If this template is used:

1) CDEs in black Calibri are required
2) CDEs in *burnt orange Italics Calibri* are required if the condition is met
3) CDEs in blue Times New Roman are recommended but not required

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Respiratory Assist Device Face-to-Face (F2F) Encounter Template

Patient information:

Last name: _____First name: _____MI: _____

DOB (MM/DD/YYYY):_____ Gender: ____M ___F ___Other Medicare ID:_____

Provider (physician/NPP) who performed the F2F evaluation if different from the signing provider:

*Last name:*_____*First name:* _____*MI:* ___*Suffix:*_____

*NPI:*_____

Date of encounter (MM/DD/YYYY):_____

Is this a F2F evaluation of the patient's need for RAD therapy? _____Yes _____No

If Yes, is this ___ an initial evaluation or ___ a re-evaluation?

If re-evaluation, is there evidence of continued use of the RAD and accessories?

____Yes ____No Describe:_____

*If No, purpose of the encounter:*_____

Patient Diagnoses related to need for RAD Therapy (check all that apply):

_____Restrictive thoracic disorder ____Severe COPD ____Hypoventilation syndrome

_____Central sleep apnea ____Complex sleep apnea ____Obstructive sleep apnea (OSA)

Other Diagnoses

ICD-10	Description

Current sleep study results if available (If re-evaluation, result of prior sleep study):

Apnea-Hypopnea Index (AHI) _____ in events/hour

Symptoms: ___excessive daytime sleepiness, ___impaired cognition, ___mood disorder, ___insomnia,

*___other, describe*_____

History: ___hypertension, ____ischemic heart disease, ____history of stroke,

___other, describe _____

*Date of study (MM/DD/YYYY):*_____ *Was study performed in a facility? _____Yes ____No*

Other qualifying observations:

If patient has a neuromuscular disease only:

Maximal inspiratory pressure: _____cm H20 and/or forced vital capacity: _____% predicted

If patient has severe COPD:

OSA and treatment with a CPAP was considered and ruled out: ___Yes ___No

Describe: _____

If patient has CSA or CompSA:

Was significant improvement of sleep associated hypoventilation with use of an E0470 or E0471 while breathing the usual FIO2? ____Yes ___No

Describe: _____

If patient has Hypoventilation Syndrome:

Spirometry results: FEV1/FVC: _____% and FEV1: _____% predicted

If patient has Obstructive Sleep Apnea:

Was E0601 (CPAP) tried and not effective on therapeutic trial conducted in either a

____ facility, or _____in a home setting? ____Yes ____No

E0601 patient is not tolerating the therapy at current settings and lower pressures settings were tried and failed to: ____adequately control the symptoms of OSA, ___ improve sleep quality, or ____reduce the AHI/RDI to acceptable levels

Note: E0471 is not covered for diagnosis of OSA

Have you reviewed and signed the written report of adherence data? ___Yes ___No

Did patient use the RAD >= 4 hours per night on 70% of nights during consecutive 30-day period during the first three months of initial use? ___Yes ___No

Is the patient capable of being trained to use the device in an appropriate manner? ___Yes ___No

If no, is there a responsible care giver? ___Yes ___No

Chief complaint / history of present illness and associated signs / symptoms:_____

_____

_____

Related past medical / surgical history:_____

_____

Medications (Status: N=New, C=Current, M=Modified, D=Discontinued)

RxNorm	Description	Dose	Frequency	Route	Status

Other medications

Allergies (Include RxNorm if known)

RxNorm	Description	RxNorm	Description

Review of systems (Significant as per history of present problem and need for a RAD Therapy):

General: ___weight gain, ___weight loss, ___sleeping problems, ___fatigue, ___fever, ___chills, ___night sweats / diaphoresis
___other:_____

Skin: ___pressure ulcers, ___rashes, ___changes in nails/hair, ___eczema, ___pruritus,
___other:_____

Lymphatic: ___swollen glands/masses: ___in the neck, ___axilla, ____groin,
___other:_____

Head: ___fainting, ___dizziness, ____headaches,
___other:_____

Eyes: ___diplopia, ___glasses/contact lenses, ___redness/discharge, ___blurred vision, ___glaucoma, ___cataracts,
___other:_____

Ears: ___tinnitus, ___discharge, ___hearing loss,
___other:_____

Nose: ___epistaxis, ____sinus infections, ___discharge, ____polyps,
___other:_____

Oral: ___dysphagia, ___hoarseness, ___teeth/dentures,
___other:_____

Neck: ___lumps, ___pain on movement
___other:_____

Breast:	___masses/tumors, ___tenderness, ___discharge, ___gynecomastia, ___other:_____
Pulmonary:	___cough, ___shortness of breath, ___pain, ___wheezing, ___hemoptysis, ___sputum production ___other:_____
Cardiac:	___chest pain, ___palpitations, ___orthopnea, ___murmur, ___syncope ___other:_____
Vascular:	___edema, ___claudication, ___varicose veins, ___thrombophlebitis, ___ulcers ___other:_____
Gastrointestinal:	___swallowing problems, ___abdominal pain, ___constipation, ___diarrhea, ___incontinence, ___nausea, ___vomiting, ___ulcers, ___melena, ___rectal bleeding, ___jaundice, ___heartburn, ___hematemesis ___other:_____
Renal:	___dysuria, ___frequency, ___urgency, ___hesitation, ___flank pain, ___hematuria, ___incontinence, ___nocturia, ___polyuria, ___other:_____
Musculoskeletal:	___pain, ___swelling, ___stiffness, ___limitation of range of motion, ___arthritis ___gout, ___cramps, ___myalgia, ___fasciculation, ___atrophy, ___fracture, ___deformity, ___weakness, ___other:_____
Neurologic:	___seizures, ___poor memory, ___poor concentration, ___numbness / tingling, ___pins and needles sensation, ___hyperpathia, ___dysesthesia, ___weakness, ___paralysis, ___tremors, ___involuntary movements, ___unstable gait, ___fall, ___vertigo, ___headache, ___stroke, ___speech disorders ___other:_____
Psychiatric:	___hallucinations, ___delusions, ___anxiety, ___nervous breakdown, ___mood changes ___other:_____
Hematology:	___anemia, ___bruising, ___bleeding disorders (conditional) ___other:_____
Endocrine:	___heat or cold intolerance, ___diabetes, ___lipid disorders, ___goiter ___other:_____
Other:_____ _____	

Physical examination:

Vital signs: T=_____P=_____R=_____BP=_____/_____Height=_____Weight=_____

O2 Sat:_____ (RA at Rest) O2 Sat:_____ (with supplemental O2 at _____LPM)

Neck circumference:_____ cm Body mass index (BMI)_____

General appearance:_____

Head and neck:_____

Chest / lungs:_____

Cardiovascular:_____

Abdominal:_____

Musculoskeletal / extremities:_____

Neurological:_____

Psychiatric:_____

Visual Exam:_____

Other:_____

Physician/NPP assessment / summary:_____

Treatment plan:

Orders:

Medications:

Supplies:

Investigations / diagnostic testing:

Consults:

Other:

Signature, Name, Date and NPI of physician or allowed NPP

Signature:

Name (Printed):

Date (MM/DD/YYYY): NPI: