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) 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.)

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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 Italic Calibri are required if the condition is met
3) CDEs in blue Times New Roman are recommended but not required

Version R1.0b
Use of this template is voluntary / optional

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

#### Patient information:

<table>
<thead>
<tr>
<th>Last name:</th>
<th>First name:</th>
<th>MI:</th>
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<tr>
<th>DOB (MM/DD/YYYY):</th>
<th>Gender: M  F  Other</th>
<th>Medicare ID:</th>
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#### Provider (physician/NPP) who performed the F2F evaluation if different from the signing provider:

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<th>Last name:</th>
<th>First name:</th>
<th>MI:</th>
<th>Suffix:</th>
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<th>NPI:</th>
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#### 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

<table>
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<tr>
<th>ICD-10</th>
<th>Description</th>
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#### 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)

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<tr>
<th>RxNorm</th>
<th>Description</th>
<th>Dose</th>
<th>Frequency</th>
<th>Route</th>
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Other medications

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### Allergies (Include RxNorm if known)

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### 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:
<table>
<thead>
<tr>
<th>System</th>
<th>Symptoms</th>
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<tbody>
<tr>
<td>Breast</td>
<td>masses/tumors, tenderness, discharge, gynecomastia, other:</td>
</tr>
<tr>
<td>Pulmonary</td>
<td>cough, shortness of breath, pain, wheezing, hemoptysis, sputum production</td>
</tr>
<tr>
<td>Cardiac</td>
<td>chest pain, palpitations, orthopnea, murmur, syncope</td>
</tr>
<tr>
<td>Vascular</td>
<td>edema, claudication, varicose veins, thrombophlebitis, ulcers</td>
</tr>
<tr>
<td>Gastrointestinal</td>
<td>swallowing problems, abdominal pain, constipation, diarrhea, incontinence, nausea, vomiting, ulcers, melena, rectal bleeding, jaundice, heartburn, hematemesis</td>
</tr>
<tr>
<td>Renal</td>
<td>dysuria, frequency, urgency, hesitation, flank pain, hematuria, incontinence, nocturia, polyuria,</td>
</tr>
<tr>
<td>Musculoskeletal</td>
<td>pain, swelling, stiffness, limitation of range of motion, arthritis, gout, cramps, myalgia, fasciculation, atrophy, fracture, deformity, weakness,</td>
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<tr>
<td>Neurologic</td>
<td>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,</td>
</tr>
<tr>
<td>Psychiatric</td>
<td>hallucinations, delusions, anxiety, nervous breakdown, mood changes, other,</td>
</tr>
<tr>
<td>Hematology</td>
<td>anemia, bruising, bleeding disorders (conditional), other,</td>
</tr>
<tr>
<td>Endocrine</td>
<td>heat or cold intolerance, diabetes, lipid disorders, goiter, other,</td>
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<tr>
<td>Other:</td>
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</table>
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: ______________________