Use of the Suggested Clinical Data Elements is voluntary / optional

Respiratory Assist Device F2F Encounter
Suggested Clinical Data Elements (CDEs)

Version R1.0b (4/12/2018)

Note: If these CDEs are 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

**Beneficiary Information CDEs**

**PBD: Patient/Beneficiary Demographics**

- **PBD1**: Patient’s first name, last name, and middle initial (text)
- **PBD2**: Patient’s date of birth (date: MM/DD/YYYY)
- **PBD3**: Patient’s Gender (Single selection from the value set: M, F, Other)
- **PBD4**: Patient’s Medicare ID (Medicare ID format and check digit)

**Encounter CDEs**

**PND: Physician/NPP Demographics**

If different from the signing provider

- **PND1**: Provider first name, last name, middle initial, and suffix (text).
- **PND2**: Provider NPI (Numeric with check digit)

**ENC: Encounter**

- **ENC4**: Date of encounter (date: MM/DD/YYYY)

**Diagnoses CDEs**

**RADDIAG: Respiratory Assist Device Diagnoses**

- **RADDIAG1**: Patient diagnoses for order (Multiple selection from value set: Restrictive thoracic disorder, Severe COPD, Hypoventilation syndrome, Central sleep apnea, Complex sleep apnea, Obstructive sleep apnea (OSA), Other)

**DIAG: Other patient diagnoses (repeat as necessary)**

- **DIAG1**: Diagnoses
  - **DIAG1a**: ICD10 (code) (from valid list of ICD10 codes)
  - **DIAG1b**: Description (text)
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**RADENC: RAD Encounter Information**

**RADENC1**: Is this an evaluation of the patient’s need for RAD therapy (Single selection from value set: Yes, No)

**RADENC1a**: If yes, type of evaluation (Single selection from value set: initial, re-evaluation)

**RADENC2**: If re-evaluation, is there evidence of continued use of the RAD and accessories? (Single selection from value set: Yes, No)

**RADENC2a**: Describe (text)

**RADENC1b**: If no, purpose of the encounter. (text)

**Evaluation and re-evaluation CDEs**

**RADEVAL: RAD evaluation / re-evaluation Information**

**RADEVAL1**: Apnea-Hypopnea Index (AHI) (numeric, units of events per hour)

**RADEVAL3**: Symptoms (Multiple selection from value set: excessive daytime sleepiness, impaired cognition, mood disorder, insomnia, other)

**RADEVAL3a**: Other: (text)

**RADEVAL4**: History (Multiple selection from value set: hypertension, ischemic heart disease, history of stroke, other)

**RADEVAL4a**: Other: (text)

**RADEVAL5**: Date of encounter (date: MM/DD/YYYY)

**RADEVAL6**: Was study performed in a facility? (Single selection from value set: Yes, No)

**RADEVAL: Other qualifying observations:**

**RADEVAL7**: If patient has a neuromuscular disease only:

**RADEVAL7a**: Maximal inspiratory pressure: (numeric, cm H20)

**RADEVAL7b**: forced vital capacity: (numeric, % predicted)

**RADEVAL8**: If patient has severe COPD:

**RADEVAL8a**: OSA and treatment with a CPAP was considered and ruled out: (single selection from value set: Yes, No)

**RADEVAL8b**: Describe: (text)

**RADEVAL9**: If patient has CSA or CompSA:

**RADEVAL9a**: as significant improvement of sleep associated hypoventilation with use of an E0470 or E0471 while breathing the usual FIO2? (single selection from value set: Yes, No)

**RADEVAL9b**: Describe: (text)
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**RADEVAL10**: If patient has Hypoventilation Syndrome: Spirometry results

- **RADEVAL10a**: FEV1/FVC: (numeric, %)
- **RADEVAL10b**: FEV1: (numeric, % predicted)

**RADEVAL11**: If patient has Obstructive Sleep Apnea:

- **RADEVAL11a**: Was E0601 (CPAP) tried and not effective on therapeutic trial conducted in
  - (Single selection from value set: facility, home)
- **RADEVAL11b**: E0601 patient not tolerating the therapy at current settings and lower pressure settings were tried and failed to
  - (Multiple selection from value set: adequately control the symptoms of OSA, improve sleep quality, reduce the AHI/RDI to acceptable levels)

**RADEVAL12**: Have you reviewed and signed the written report of adherence data

- **RADEVAL13**: 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

Note: E0471 is not covered for a diagnosis of OSA

**Subjective CDEs**

- **RADEVAL14**: Is the patient capable of being trained to use the device in an appropriate manner
- **RADEVAL14a**: If no, is there a responsible care giver

**SUB**: Subjective

- **SUB1**: Chief complaint / history of present illness and associated signs / symptoms
- **SUB2**: Related past medical / surgical history

**MED**: Medications (Status value set: New, Current, Modified, Discontinued)

- **MEDI1**: Medications
- **MEDI2**: Other Medications

**ALL**: Allergies (include RxNorm if Known)

- **ALL1**: Allergies
Review of Systems CDEs

ROS: Review of Systems (Multiple selection from all of the following elements, ROS1-ROS21 and value set following each)

ROS1: General: weight gain, weight loss, sleeping problems, fatigue, fever, chills, night sweats/diaphoresis
ROS1a: other: (text)

ROS2: Skin: pressure ulcers, rashes, changes in nails/hair, eczema, pruritus
ROS2a: other: (text)

ROS3: Lymphatic: swollen glands/masses (in the neck, axilla, groin)
ROS3a: other: (text)

ROS4: Head: fainting, dizziness, headaches
ROS4a: other: (text)

ROS5: Eyes: diplopia, glasses/contact lenses, redness/discharge, blurred vision, glaucoma, cataracts
ROS5a: other: (text)

ROS6: Ears: tinnitus, discharge, hearing loss
ROS6a: other: (text)

ROS7: Nose: epistaxis, sinus infections, discharge, polyps
ROS7a: other: (text)

ROS8: Oral: dysphagia, hoarseness, teeth/dentures
ROS8a: other: (text)

ROS9: Neck: lumps, pain on movement
ROS9a: other: (text)

ROS10: Breast: masses/tumors, tenderness, discharge, gynecomastia
ROS10a: other: (text)

ROS11: Pulmonary: cough, shortness of breath, pain, wheezing, hemoptysis, sputum production
ROS11a: other: (text)

ROS12: Cardiac: chest pain, palpitations, orthopnea, murmur, syncope
ROS12a: other: (text)

ROS13: Vascular: edema, claudication, varicose veins, thrombophlebitis, ulcers
ROS13a: other: (text)

ROS14: Gastrointestinal: swallowing problems, abdominal pain, constipation, diarrhea, incontinence, nausea, vomiting, ulcers, melena, rectal bleeding, jaundice, heartburn, hematemesis
ROS14a: other: (text)
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ROS15: Renal: dysuria, frequency, urgency, hesitation, flank pain, hematuria, incontinence, nocturia, polyuria
   ROS15a: other: (text)

ROS16: Musculoskeletal: pain, swelling, stiffness, limitation of range of motion, arthritis, gout, cramps, myalgia, fasciculation, atrophy, fractures, deformity, weakness
   ROS16a: other: (text)

ROS17: Neurologic: seizures, poor memory, poor concentration, numbness/tingling, pins and needles sensation, hyperpathia, dysesthesia, weakness, paralysis, tremors, involuntary movements, unstable gait, falls, vertigo, headaches, stroke, speech disorders
   ROS17a: other: (text)

ROS18: Psychiatric: hallucinations, delusions, anxiety, nervous breakdown, mood changes
   ROS18a: other: (text)

ROS19: Hematology: anemia, bruising, bleeding disorders (conditional)
   ROS19a: other: (text)

ROS20: Endocrine: heat or cold intolerance, diabetes, lipid disorders, goiter
   ROS20a: other: (text)

ROS21: Other: (text)

**Objective / Physical Exam CDEs**

OBJ: Objective / Physical Exam:

   **OBJ1:** Vital Signs:
     **OBJ1a:** Temperature: (numeric and units)
     **OBJ1b:** Pulse: (numeric – beats per minute)
     **OBJ1c:** Respiration: (numeric – breaths per minute)
     **OBJ1d:** Blood Pressure:
       Systolic: (numeric – mm of mercury)
       Diastolic: (numeric – mm of mercury)
     **OBJ1e:** Height: (single part: numeric and units or two part with numeric and units for each)
     **OBJ1f:** Weight: (single part: numeric and units or two part with numeric and units for each)
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RADOBJ: PAP O2 Measurements
- **RADOBJ1**: O2 Sat (RA at Rest) (Numeric, %)
- **RADOBJ2**: O2 Sat (with supplemental O2) (Numeric, %)
- **RADOBJ2a**: Supplemental O2 (Numeric, LPM)

RADOBJ: RAD Objective
- **RADOBJ3**: Neck circumference (numeric, cm)
- **RADOBJ4**: Body mass index (BMI) (Numeric)

OBJ: Objective / Physical Exam:
- **OBJ2**: General Appearance: (text)
- **OBJ3**: Head and Neck: (text)
- **OBJ4**: Chest/lungs: (text)
- **OBJ5**: Cardiovascular: (text)
- **OBJ6**: Abdominal: (text)
- **OBJ7**: Musculoskeletal / extremities: (text)
- **OBJ8**: Neurological: (text)
- **OBJ9**: Psychiatric: (text)
- **OBJ10**: Visual Exam: (text)
- **OBJ11**: Other: (text)

**Assessment and Plan CDEs**

ASM: Assessment
- **ASM1**: Assessment/Status (text)

PLAN: Treatment Plan
- **PLAN1**: Treatment Plan (text)

ORD: Orders
- **ORD1**: Medications: (text)
- **ORD2**: Supplies: (text)
- **ORD3**: Investigations / diagnostic testing: (text)
- **ORD4**: Consults: (text)
- **ORD5**: Other: (text)
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**Provider Signature CDEs**

**SIGPNP:** Physician/NPP Signature Elements

- **SIGPNP1:** Physician/NPP Signature (image, electronic, or digital)
- **SIGPNP2:** Physician/NPP Printed Name (text)
- **SIGPNP5:** Date of Signature (MM/DD/YYYY)
- **SIGPNP4:** Physician/NPP NPI (NPI format)