DRAFT

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

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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) (Single selection from value set: Yes, No)

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 (Single selection from value set: Yes, No)

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 (Single selection from value set: Yes, No)

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 (Single selection from value set: Yes, No)

RADEVAL14a: If no, is there a responsible care giver (Single selection from value set: Yes, No)

SUB: Subjective

SUB1: Chief complaint / history of present illness and associated signs / symptoms (text)

SUB2: Related past medical / surgical history (text)

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

MED1: Medications (Repeat until complete: RxNorm, Description, Dose, Frequency, Route, Status)

MED2: Other Medications (text)

ALL: Allergies (include RxNorm if Known)

ALL1: Allergies (RxNorm, Description …)

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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)