Use of the Suggested Clinical Data Elements is voluntary / optional

External Infusion Pump F2F Encounter
Suggested Clinical Data Elements (CDEs)
Version R1.0a (4/30/2018)

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)

F2F Encounter CDEs

PND: Physician/NPP Demographics

If different than 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 F2F encounter (date: MM/DD/YYYY)

F2F Encounter Question CDEs

NEBENC: External Infusion Pump Encounter

HOTENC1: Is this a F2F encounter for the evaluation of a patient's need of a Continuous Subcutaneous Insulin Infusion (CSII) Pump? (Single selection from value set: Yes, No)

HOTENC1: Is this an in-person encounter for the evaluation of the patient's need for an external infusion pump for drugs other than CSII? (Single selection from value set: Yes, No)

HOTENC1a: If no, describe purpose. (text)

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Diagnoses CDEs

EIPDIAG: External Infusion Pump Medical Condition / Diagnoses

Note: for each medical condition / diagnosis

> ***EIPDIAG1**: Patient medical condition / diagnosis (Multiple selection from value set: Treatment of diabetes; Immunodeficiency; Pulmonary hypertension; Hypercalcemia; Parkinson's disease; Acute lymphoblastic leukemia, in relapse; Chronic iron overload; Intractable/chronic pain, Chemotherapy; Stage D heart failure - inotropic therapy; Anti-viral; Anti-fungal; Other)*
>> If Other, **EIPDIAG1a**: Other (text)
> **EIPDIAG2**: ICD-10 code (Multiple selection from diagnosis value set)

External Infusion Pump Requirements

EIPREQ: External Infusion Pump for Continuous Subcutaneous Insulin Infusion (CSII)

Requirement for an external infusion pump for a Continuous Subcutaneous Insulin Infusion (CSII) Pump:

CSII Requirements:

> ***EIPREQ3**: Patient is beta cell autoantibody positive (Single selection: checked (Yes), No)*
> ***EIPREQ2**: Patient is insulinopenic based on (Multiple selection from value set: a fasting C-peptide level that is less than or equal to 110% of the lower limit of normal of the laboratory's measurement method, and/or; patient has renal insufficiency (as documented in the medical record) and creatinine clearance ≤50 ml/minute, and a fasting C-peptide level that is less than or equal to 200% of the lower limit of normal of the laboratory's measurement method; A fasting blood sugar obtained at the same time as the C-peptide level is less than or equal to 225 mg/dL. (required))*
>> ***EIPREQ2a**: Creatine clearance (numeric, units: ml/min)*
>> ***EIPREQ2b**: C-peptide (numeric, units: ng/ml)*
>> ***EIPREQ2b1**: Lab lower limit (numeric, units: ng/ml)*

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EIPREQ3*: Criteria A: The patient has completed a comprehensive diabetes education program, and has been on a program of multiple daily injections of insulin (i.e., at least 3 injections per day), with frequent self-adjustments of insulin doses for at least 6 months prior to initiation of the insulin pump, and has documented frequency of glucose self-testing an average of at least 4 times per day during the 2 months prior to initiation of the insulin pump, and meets one or more of the following criteria while on the multiple daily injection regimen (Single selection: checked (Yes), No)*

EIPREQ3a*: (Single selection from value set: Glycosylated hemoglobin level (HbAlc) >7.0%, history of recurring hypoglycemia, wide fluctuations in blood glucose before mealtime, and dawn phenomenon with fasting blood sugars frequently exceeding 200 mg/dl;* **or** *history of severe glycemic excursions)*

EIPREQ3a*: HbA1c (numeric, units %)*

EIPREQ4*: The patient has diabetes and has been on a pump prior to enrollment in Medicare and has documented frequency of glucose self-testing an average of at least 4 times per day during the month prior to Medicare enrollment (Single selection: checked (Yes), No)*

Non-CSII Requirements:

Requirement for an external infusion pump for other than CSII (check all that apply):

EIPREQ5*: Common requirements (Multiple selection from value set: Parenteral administration of the drug in the home is reasonable and necessary; An infusion pump is necessary to safely administer the drug)*

EIPREQ6*: Criteria 1 (Multiple selection from value set: The drug is administered by a prolonged infusion of at least 8 hours because of proven improved clinical efficacy; The therapeutic regimen is proven or generally accepted to have significant advantages over intermittent bolus administration regimens or infusions lasting less than 8 hours)*

EIPREQ7*: Criteria 2 (Multiple selection from value set: The drug is administered by intermittent infusion (each episode of infusion lasting less than 8 hours) which does not require the beneficiary to return to the physician's office prior to the beginning of each infusion; Systemic toxicity or adverse effects of the drug are unavoidable without infusing it at a strictly controlled rate as indicated in the Physician's Desk Reference, or the U.S. Pharmacopeia Drug Information)*

Note: See Appendix A for coverage requirements for medical conditions and drugs that are administered by external infusion pumps

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Subjective CDEs

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 …)

Review of Systems CDEs

ROS: Review of Systems (Multiple selection from all 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)

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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)

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)

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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

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)

External Infusion Pump Assessment and Plan CDEs

ASM: Assessment

ASM1: Assessment/Status (text)

PLAN: Treatment Plan

PLAN1: Treatment Plan (text)

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External Infusion Pump/Drugs Order CDEs

EIPORD: External Infusion Pump/Drugs Order (from fixed diagnosis list and other)

EIPORD1: Medical Condition (multiple selection from medical condition value set) (see above)

EIPORD3: Drug (Multiple selection from the drug value set) (see appropriate values)

EIPORD4: HCPCS code for the drug (pre-assigned or text entry for other)

EIPORD5a: Route (single selection from value set: SQ, IM, IP)

EIPORD5b: Concentration (numeric in mg or units /ml)

EIPORD5c: Volume (numeric in ml)

EIPORD5d: Duration (numeric in minutes, hours or continuous)

EIPORD5e: Frequency (text or numeric in times per day)

EIPORD5f: Quantity (numeric in amount(ug/mg/units), volume in ml, length days/weeks)

EIPORD5g: Refills (numeric)

EIPORD6: External Infusion Pump (Multiple selection from the external infusion value set for the specific drug(s) (see appendix A for appropriate values)

EIPORD7: IV Pole (Single selection: checked (Yes), No)

EIPORD8: Other accessories or options (text)

ORD: Orders

ORD1: Medications: (text)

ORD2: Supplies: (text)

ORD3: Investigations (Diagnostic testing): (text)

ORD4: Consults: (text)

ORD5: Other: (text)

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)