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

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)

HOTENC1a: If no, describe purpose. (text)
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)
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, hematemeses  
**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, dyesthesias, 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)