noridian
Healthcare Solutions

Documentation Checklist
External Infusion Pumps

Reference: L33794, A52507

All Claims for External Ambulatory Infusion Pumps, Insulin (E0784)

- ☐ Face-to-Face Examination (F2F)
  - ☐ Date stamp indicating supplier's date of receipt of F2F on or before date of delivery
- ☐ Written Order Prior to Delivery (WOPD)
  - ☐ Date stamp indicating supplier's date of receipt of WOPD on or before date of delivery

All other claims for infusion pumps, IV poles, supplies and drugs

- ☐ Dispensing Order, if applicable
- ☐ Detailed Written Order (DWO)

All Pumps, IV poles, Supplies, Drugs

- ☐ DME Information Form (DIF) – CMS-10125
- ☐ Beneficiary Authorization
- ☐ Refill Requirements
- ☐ Proof of Delivery (POD)
  - ☐ Method 1 - Direct Delivery to the Beneficiary by the Supplier
    The date the beneficiary/designee signs for the supplies is to be the date of service of the claim.
  - ☐ Method 2 - Delivery via Shipping or Delivery Service
    The shipping date is to be the date of service of the claim.
- ☐ Continued Need
- ☐ Continued Use

Medical Records

- ☐ Medical Records Supporting Basic Coverage Criteria
  - ☐ E0779, E0780, E0781, and E0791 are covered for indications I-III, V(A) - V(D), V(F), V(G), V(I), and V(J). Coverage of other pumps is addressed under indications IV, V(E), and V(H).
    - ☐ I. Deferoxamine for chronic iron overload
    - ☐ II. Chemotherapy for primary hepatocellular carcinoma or colorectal cancer where it's unresectable or the beneficiary (bene) refuses excision

- ☐ III. Morphine for intractable pain caused by cancer
- ☐ IV. Continuous subcutaneous insulin for diabetes if A or B is met and if C or D is met (administered with E0784):
  - ☐ A. C-peptide testing requirement-must meet criterion 1 or 2 and 3:
    - ☐ 1. C- peptide ≤ 110% of the lower limit of normal of the lab's method, **or**
    - ☐ 2. For benes with renal insufficiency and a creatinine clearance ≤ 50 ml/minute, a fasting C-peptide level is ≤ 200% of the lower limit of normal of the lab's method, **and**
    - ☐ 3. A fasting blood sugar obtained at the same time as the C-peptide level is ≤ 225 mg/dl **or**
  - ☐ B. Beta cell autoantibody test is positive **and**
  - ☐ C. The bene has completed a diabetes education program, has been on multiple daily injections of insulin with frequent self-adjustments for at least 6 months prior to insulin pump use, and has documented glucose self-testing an average of at least 4 times/day during the 2 months prior to pump use, and meets one or more of the following criteria (1-5) while on multiple injection regimen:
    - ☐ 1. HbA1C > 7%
    - ☐ 2. History of recurring hypoglycemia
    - ☐ 3. Wide fluctuations in blood glucose before mealtime
    - ☐ 4. Dawn phenomenon with fasting blood sugars frequently > 200 mg/dL
    - ☐ 5. History of severe glycemic excursions **or**
  - ☐ D. Has been on a pump prior to enrollment to Medicare and has self-testing an average of at least 4 times/day during the month prior to Medicare enrollment
  - ☐ Continued coverage of an external insulin pump and supplies requires that the beneficiary be seen and evaluated by the treating physician at least every 3 months
- ☐ V. Administration of other drugs if either of the following sets of criteria (1) or (2) are met:
  - ☐ Criteria set 1:
    - ☐ Parenteral administration in the home is reasonable and necessary
    - ☐ An infusion pump is necessary to safely administer the drug
    - ☐ Administered by infusion ≥ 8 hours because of proven improved efficacy
    - ☐ Significant advantages over intermittent bolus infusions lasting < 8 hours **or**
  - ☐ Criteria set 2:
    - ☐ Parenteral administration of the drug in the home is reasonable and necessary
    - ☐ An infusion pump is necessary to safely administer the drug
    - ☐ Administered by intermittent infusion which does not require the bene to return to the physician's office prior to each infusion
    - ☐ 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

☐ Administration of other drugs, based on criteria set (1) or (2), is limited to the following situations A-J:

- ☐ A. Anticancer chemotherapy drugs cladribine, fluorouracil, cytarabine, bleomycin, floxuridine, doxorubicin (non-liposomal), vincristine (non-liposomal) or vinblastine by continuous infusion over ≥ 8 hours when the regimen has significant advantages over intermittent regimens
- ☐ B. Narcotic analgesics (except meperidine) in place of morphine to a bene with intractable pain caused by cancer that has not responded to and/or cannot tolerate an adequate oral/transdermal therapeutic regimen
- ☐ C. Antifungal or antiviral drugs: acyclovir, foscarnet, amphotericin B, and ganciclovir
- ☐ D. Parenteral inotropic therapy (for services provided on/after 12/01/2015), using the drugs dobutamine, milrinone and/or dopamine for beneficiaries with American College of Cardiology Foundation/American Heart Association Stage D heart failure (HF) or New York Heart Association Class IV HF if all of the following are met (for services provided prior to 12/01/2015 see the superseded LCD/PA):
  - ☐ 1. Remains symptomatic despite optimal guideline directed medical therapy (GDMT); **and**
  - ☐ 2. As "Bridge" therapy for patients eligible for and awaiting mechanical circulatory support (MCS)/cardiac transplantation, or as palliative care for patients not eligible for either MCS/cardiac transplantation; **and**
  - ☐ 3. Prescribed following an evaluation by a cardiologist with training in the management of advanced heart failure; **and**
  - ☐ 4. There has been a documented improvement in beneficiary symptoms of heart failure while on the selected inotropic drug at the time of discharge from an inpatient or skilled nursing care facility; **and**
  - ☐ 5. An evaluation every three months by the prescribing provider or a heart failure team with oversight by a cardiologist with training in the management of advanced heart failure, which documents the beneficiary's cardiac symptoms and the continuing response and need for therapy. The heart failure team or physician may have no financial relationship with the supplier.
- ☐ E. Epoprostenol (J1325) or treprostinil (J3285) for pulmonary hypertension if they meet the following disease criteria (administered using K0455):
  - ☐ 1. The pulmonary hypertension is not secondary to pulmonary venous hypertension or disorders of the respiratory system; **and**
  - ☐ 2. Primary pulmonary hypertension or pulmonary hypertension is secondary to one of the following conditions: connective tissue disease, thromboembolic disease of the pulmonary arteries, HIV, cirrhosis, diet drugs, congenital left to right shunts, etc. If these conditions are present, the following criteria must be met:
    - ☐ a. Pulmonary hypertension has progressed despite maximal medical and/or surgical treatment; **and**
    - ☐ b. Mean pulmonary artery pressure > 25 mm Hg at rest or > 30 mm Hg with exertion; **and**
    - ☐ c. Significant symptoms from the pulmonary hypertension; **and**
    - ☐ d. Treatment with oral calcium channel blocking agents has been tried and failed, or has been considered and ruled out

☐ F. Gallium nitrate (J1457) for symptomatic cancer-related hypercalcemia.

☐ G. Ziconotide (J2278) for the management of severe chronic pain for whom intrathecal (IT or epidural) therapy is warranted, and who are intolerant of or refractory to other treatment

☐ H. Subcutaneous immune globulin (J1559, J1561, J1562, J1569) only if criteria 1 **and** 2 are met (administered with E0779):

- ☐ 1. The subcutaneous immune globulin preparation is a pooled plasma derivative which is approved for the treatment of primary immune deficiency disease; **and**
- ☐ 2. The bene has a diagnosis of primary immune deficiency disease
- ☐ Coverage of subcutaneous immune globulin apples only to subcutaneous administration products.

☐ I. Levodopa-Carbidopa enteral suspension (J7799) for treatment of motor fluctuations in beneficiaries with Parkinson's disease (PD), who meet all of the following criteria:

- ☐ 1. The beneficiary has been evaluated by a neurologist, who prescribes and manages treatment with the drug; **and**
- ☐ 2. Idiopathic PD based on the presence of bradykinesia and at least one other cardinal PD features (tremor, rigidity, postural instability); **and**
- ☐ 3. L-dopa responsive with clearly defined "On" periods; **and**
- ☐ 4. Persistent motor complications with disabling "Off" periods for a minimum of 3 hours/day, despite medical therapy with levodopa-carbidopa, and at least one other class of anti-PD therapy i.e. COMT inhibitor or MAO-B inhibitor.

☐ J. Blinatumomab (J7799) for treatment of adult beneficiaries with Philadelphia chromosome negative relapsed/refractory acute lymphoblastic leukemia

Billing Reminders

- JB modifier must be added to all immune globulin (J1559, J1561, J1562, J1569) and associated infusion pump (E0779) codes where the route of administration is subcutaneous.
- For all claims for external insulin infusion pumps (E0784) and insulin (J1817), if the results of the bene's C-peptide level or beta cell autoantibody test meet the requirements outlined in section IV above, a KX modifier should be added to the HCPCS code.
- When there is an expectation of a medical necessity denial for HCPCS codes E0784 and J1817, suppliers must enter the GA modifier if they have obtained a valid Advance Beneficiary Notice (ABN) or a GZ modifier if they have not obtained a valid ABN.
- Claim lines for E0784 and J1817 billed without a KX, GA, or GZ modifier will be rejected as missing information.
- Use the unclassified drug code J7799 if the drug used in the durable external infusion pump does not have a distinct code.
- Codes E0784, J1457, J1559, J1561, J1562, J1569, J1817, and J7799, when used for levodopa-carbidopa enteral suspension or blinatumomab, must be billed with an appropriate ICD code if the coverage criteria are met.

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