

## LCD for External Infusion Pumps (L5044)

### Contractor Information

**Contractor Name**

TriCenturion

**Contractor Number**

77011

**Contractor Type**

DME PSC

**DME MAC this DME PSC is affiliated with**

AdminaStar Federal, Inc., National Heritage Insurance Co.

### LCD Information

**LCD ID Number**

L5044

**LCD Title**

External Infusion Pumps

**Contractor's Determination Number**

EIP20070101

**AMA CPT / ADA CDT Copyright Statement**

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**CMS National Coverage Policy**

CMS Pub. 100-3, (National Coverage Determinations Manual), Chapter 1, Section 280.14

**Primary Geographic Jurisdiction**

Connecticut  
District of Columbia  
Delaware  
Illinois  
Indiana  
Kentucky  
Massachusetts

Maryland  
Maine  
Michigan  
Minnesota  
New Hampshire  
New Jersey  
New York - Entire State  
Ohio  
Pennsylvania  
Rhode Island  
Virginia  
Vermont  
Wisconsin  
West Virginia

**Oversight Region**

Central Office

**DME Region LCD Covers**

Jurisdiction A/B

**Original Determination Effective Date**

For services performed on or after 10/01/1993

**Original Determination Ending Date**

**Revision Effective Date**

For services performed on or after 01/01/2007

**Revision Ending Date**

**Indications and Limitations of Coverage and/or Medical Necessity**

For any item to be covered by Medicare, it must 1) be eligible for a defined Medicare benefit category, 2) be reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member, and 3) meet all other applicable Medicare statutory and regulatory requirements. For the items addressed in this medical policy, the criteria for "reasonable and necessary" are defined by the following indications and limitations of coverage and/or medical necessity.

For an item to be covered by Medicare a written signed and dated order must be received by the supplier before a claim is submitted. If the supplier bills for an item addressed in this policy without first receiving the completed order, the item will be denied as not medically necessary.

An external infusion pump (E0779, E0780, E0781, E0784, E0791, K0455) is covered for the following indications (I-V):

- I. Administration of deferoxamine for the treatment of chronic iron overload.

- II. Administration of chemotherapy for the treatment of primary hepatocellular carcinoma or colorectal cancer where this disease is unresectable or where the patient refuses surgical excision of the tumor. Anticancer chemotherapy drugs used in these conditions are not required to meet the criteria described by indication V, situation A.
  
- III. Administration of morphine when used in the treatment of intractable pain caused by cancer.
  
- IV. Administration of continuous subcutaneous insulin for the treatment of diabetes mellitus (ICD-9 codes 250.00-250.93) if criterion A or B is met and if criterion C or D is met:
  - A. C-peptide testing requirement – must meet criterion 1 or 2 and criterion 3:
    - 1. C-peptide level is less than or equal to 110 percent of the lower limit of normal of the laboratory's measurement method.
    - 2. For patients with renal insufficiency and a creatinine clearance (actual or calculated from age, weight, and serum creatinine) less than or equal to 50 ml/minute, a fasting C-peptide level is less than or equal to 200 per cent of the lower limit of normal of the laboratory's measurement method.
    - 3. A fasting blood sugar obtained at the same time as the C-peptide level is less than or equal to 225 mg/dl.
  
  - B. Beta cell autoantibody test is positive.
  
  - C. The patient has completed a comprehensive diabetes education program, 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 dose 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 (1 - 5) while on the multiple injection regimen:
    - 1. Glycosylated hemoglobin level (HbA1C) greater than 7 percent
    - 2. History of recurring hypoglycemia
    - 3. Wide fluctuations in blood glucose before mealtime

4. Dawn phenomenon with fasting blood sugars frequently exceeding 200 mg/dL
5. History of severe glycemic excursions

D. The patient has been on an external insulin infusion 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.

If criterion A or B is not met, the pump and related accessories, supplies, and insulin will be denied as not medically necessary. If criterion C or D is not met, the pump and related accessories, supplies, and insulin will be denied as not medically necessary.

Continued coverage of an external insulin pump and supplies requires that the patient be seen and evaluated by the treating physician at least every 3 months. In addition, the external insulin infusion pump must be ordered and follow-up care rendered by a physician who manages multiple patients on continuous subcutaneous insulin infusion therapy and who works closely with a team including nurses, diabetic educators, and dieticians who are knowledgeable in the use of continuous subcutaneous insulin infusion therapy.

V. Administration of other drugs if either of the following sets of criteria (1) or (2) are met:

1. 1. Criteria set 1:

- Parenteral administration of the drug in the home is reasonable and necessary.
- An infusion pump is necessary to safely administer the drug.
- 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.

2. 2. 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.
- The drug is administered by intermittent infusion (each episode of infusion lasting less than 8 hours) which does not require the patient to return to the physician's office prior to the beginning of each infusion.
- Systemic toxicity or adverse effects of the drug is unavoidable without infusing it at a strictly controlled rate as indicated in the Physicians Desk Reference, or the U.S. Pharmacopeia Drug Information.

Coverage for the administration of other drugs, based on criteria set (1) or (2), using an external infusion pump is limited to the following situations (A) - (H):

- A. Administration of the anticancer chemotherapy drugs cladribine, fluorouracil, cytarabine, bleomycin, floxuridine, doxorubicin (non-liposomal), vincristine or vinblastine by continuous infusion over at least 8 hours when the regimen is proven or generally accepted to have significant advantages over intermittent administration regimens.
  
- B. Administration of narcotic analgesics (except meperidine) in place of morphine to a patient with intractable pain caused by cancer who has not responded to an adequate oral/transdermal therapeutic regimen and/or cannot tolerate oral/transdermal narcotic analgesics.
  
- C. Administration of the following antifungal or antiviral drugs: acyclovir, foscarnet, amphotericin B, and ganciclovir. Liposomal amphotericin B preparations (J0287-J0289) are covered for patients who meet one of the following criteria:
  - 1. The patient has suffered some significant toxicity that would preclude the use of standard amphotericin B and is unable to complete the course of therapy without the liposomal form, or
  - 2. The patient has significantly impaired renal function.

If these criteria are not met, payment will be based on the allowance for the least costly medically appropriate alternative, standard amphotericin B (J0285).

D. Administration of parenteral inotropic therapy, using the drugs dobutamine, milrinone and/or dopamine for patients with congestive heart failure and depressed cardiac function if a patient meets all of the following criteria:

1. Dyspnea at rest or with minimal exertion is present despite treatment with maximum or near maximum tolerated doses of digoxin, a loop diuretic, and an angiotensin converting enzyme inhibitor or another vasodilator (e.g., hydralazine or isosorbide dinitrate), used simultaneously (unless allergic or intolerant), and
2. Doses are within the following ranges (lower doses will be covered only if part of a weaning or tapering protocol from higher dose levels):
  - a. Dobutamine - - 2.5-10 mcg/kg/min
  - b. Milrinone - - 0.375-0.750 mcg/kg/min
  - c. Dopamine - - less than or equal to 5 mcg/kg/min, and
3. Cardiac studies by either invasive hemodynamic technique or using thoracic electrical bioimpedance (impedance cardiography), performed within 6 months prior to the initiation of home inotropic therapy showing (a) cardiac index (CI) is less than or equal to 2.2 liters/min/meter squared and/or pulmonary capillary wedge pressure (PCWP) is greater than or equal to 20 mm Hg before inotrope infusion on maximum medical management and (b) at least a 20% increase in CI and/or at least a 20% decrease in PCWP during inotrope infusion at the dose initially prescribed for home infusion, and
4. There has been an improvement in patient well being, (less dyspnea, improved diuresis, improved renal function and/or reduction in weight) with the absence of dyspnea at rest at the time of discharge and the capability of outpatient evaluation by the prescribing physician at least monthly, and
5. In the case of continuous infusion, there is documented deterioration in clinical status when the drug(s) is tapered or discontinued under observation in the hospital, or in the case of intermittent infusions, there is documentation of repeated hospitalizations for congestive heart failure despite maximum medical management, and
6. Any life threatening arrhythmia is controlled prior to hospital discharge and there is no need for routine electrocardiographic monitoring at home, and
7. The patient is maintained on the lowest practical dose and efforts to decrease the dose of the drug(s) or the frequency/duration of infusion are documented during the first 3 months of therapy, and
8. The patient's cardiac symptoms, vital signs, weight, lab values, and response to therapy are routinely assessed and documented in the patient's medical record.

E. Administration of epoprostenol (J1325) or treprostinil (J3285) for patients with pulmonary hypertension if they meet the following disease criteria:

1. The pulmonary hypertension is not secondary to pulmonary venous hypertension (e.g., left sided atrial or ventricular disease, left sided valvular heart disease, etc.) or disorders of the respiratory system (e.g., chronic obstructive pulmonary disease, interstitial lung disease, obstructive sleep apnea or other sleep disordered breathing, alveolar hypoventilation disorders, etc.); and
2. The patient has primary pulmonary hypertension or pulmonary hypertension which is secondary to one of the following conditions: connective tissue disease, thromboembolic disease of the pulmonary arteries, human immunodeficiency virus (HIV) infection, cirrhosis, diet drugs, congenital left to right shunts, etc. If these conditions are present, the following criteria must be met:
  - a. The pulmonary hypertension has progressed despite maximal medical and/or surgical treatment of the identified condition; and
  - b. The mean pulmonary artery pressure is greater than 25 mm Hg at rest or greater than 30 mm Hg with exertion; and
  - c. The patient has significant symptoms from the pulmonary hypertension (i.e., severe dyspnea on exertion, and either fatigability, angina, or syncope); 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) is covered for the treatment of symptomatic cancer-related hypercalcemia (ICD-9 275.42). In general, patients with a serum calcium (corrected for albumin) less than 12 mg/dl would not be expected to be symptomatic.

The recommended usage for gallium nitrate is daily for five consecutive days. Use for more than 5 days will be denied as not medically necessary.

More than one course of treatment for the same episode of hypercalcemia will be denied as not medically necessary.

G. Ziconotide (J2278) is covered for the management of severe chronic pain in patients for whom intrathecal (IT or epidural) therapy is warranted, and who are intolerant of or refractory to other treatment, such as systemic analgesics, adjunctive therapies, or IT morphine.

H. Subcutaneous immune globulin (J1562) is covered only if criteria 1 and 2 are met:

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 patient has a diagnosis of primary immune deficiency disease (ICD-9 codes 279.04, 279.05, 279.06, 279.12, 279.2).

Coverage of subcutaneous immune globulin applies only to those products that are specifically labeled as subcutaneous administration products. Intravenous immune globulin products are not covered under this LCD.

External infusion pumps and related drugs and supplies will be denied as not medically necessary when the criteria described by indication (I), (II), (III), (IV) or (V) are not met.

When an infusion pump is covered, the drug necessitating the use of the pump and necessary supplies are also covered. When a pump has been purchased by the Medicare program, other insurer, or the patient, or the rental cap has been reached, the drug necessitating the use of the pump, and supplies are covered as long as the coverage criteria for the pump are met.

Medicare only pays for one pump (K0455) for administering epoprostenol and treprostinil; the supplier is responsible for ensuring that there is an appropriate and acceptable contingency plan to address any emergency situations or mechanical failures of the equipment. A second pump provided as a backup will be denied as not medically necessary.

An external infusion pump and related drugs and supplies will be denied as not medically necessary in the home setting for the treatment of thromboembolic disease and/or pulmonary embolism by heparin infusion.

An infusion controller device (E1399) is not medically necessary.

An IV pole (E0776) is covered only when a stationary infusion pump (E0791) is covered. It is considered not medically necessary if it is billed with an ambulatory infusion pump (E0779, E0780, E0781, E0784, or K0455).

Supplies for the maintenance of a parenteral drug infusion catheter (A4221) are covered during the period of covered use of an infusion pump. They are also covered for the weeks in between covered infusion pump use, not to exceed 4 weeks per episode.

Supplies used with an external infusion pump, A4222 or K0552, are covered during the period of covered use of an infusion pump. Allowance is based on the number of cassettes or bags (A4222) prepared or syringes (K0552) used. For intermittent infusions, no more than one cassette or bag is covered for each dose of drug. For continuous infusion, the concentration of the drug and the size of the cassette, bag, or syringe should be maximized to result in the fewest cassettes, bags, or syringes in keeping with good pharmacologic and medical practice.

Drugs and supplies that are dispensed but not used for completely unforeseen circumstances (e.g., emergency admission to hospital, drug toxicity, etc.) are covered. Suppliers are expected to anticipate changing needs for drugs (e.g., planned hospital admissions, drug level testing with possible dosage change, etc.) in their drug and supply preparation and delivery schedule.

Supplies used with an external insulin infusion pump are covered during the period of covered use of an infusion pump and are billed using code A4221 and K0552. Charges for drugs administered by a DME infusion pump may only be billed by the entity that actually dispenses the drug to the Medicare beneficiary and that entity must be permitted under all applicable federal, state, and local laws and regulations to dispense drugs. Only entities licensed in the state where they are physically located may bill the DMERC for infusion drugs. Drugs and related supplies and equipment billed by a supplier who does not meet these criteria will be denied as not medically necessary.

#### **Coverage Topic**

Ambulatory Surgical Centers

### **Coding Information**

#### **CPT/HCPCS Codes**

**The appearance of a code in this section does not necessarily indicate coverage.**

#### **HCPCS MODIFIERS:**

**EY – No physician or other licensed health care provider order for this item or service**

**GY - Item or service statutorily excluded or does not meet the definition of any Medicare benefit.**

**KX - Specific required documentation on file.**

#### **EQUIPMENT**

E0776 IV POLE

E0779 AMBULATORY INFUSION PUMP, MECHANICAL, REUSABLE, FOR INFUSION 8 HOURS OR GREATER

E0780 AMBULATORY INFUSION PUMP, MECHANICAL, REUSABLE, FOR INFUSION LESS THAN 8 HOURS

E0781 AMBULATORY INFUSION PUMP, SINGLE OR MULTIPLE CHANNELS, ELECTRIC OR BATTERY OPERATED, WITH ADMINISTRATIVE EQUIPMENT, WORN BY PATIENT

E0784 EXTERNAL AMBULATORY INFUSION PUMP, INSULIN

E0791 PARENTERAL INFUSION PUMP, STATIONARY, SINGLE OR MULTI-CHANNEL

E1399 DURABLE MEDICAL EQUIPMENT, MISCELLANEOUS

K0455 INFUSION PUMP USED FOR UNINTERRUPTED PARENTERAL ADMINISTRATION OF MEDICATION, (E.G., EPOPROSTENOL OR TREPROSTINOL)

### **SUPPLIES**

A4221 SUPPLIES FOR MAINTENANCE OF DRUG INFUSION CATHETER, PER WEEK (LIST DRUG SEPARATELY)

A4222 INFUSION SUPPLIES FOR EXTERNAL DRUG INFUSION PUMP, PER CASSETTE OR BAG (LIST DRUGS SEPARATELY)

A4223 INFUSION SUPPLIES NOT USED WITH EXTERNAL INFUSION PUMP, PER CASSETTE OR BAG (LIST DRUGS SEPARATELY)

A4305 DISPOSABLE DRUG DELIVERY SYSTEM, FLOW RATE OF 50 ML OR GREATER PER HOUR

A4306 DISPOSABLE DRUG DELIVERY SYSTEM, FLOW RATE OF LESS THAN 50 ML PER HOUR

A9270 NON-COVERED ITEM OR SERVICE

K0552 SUPPLIES FOR EXTERNAL DRUG INFUSION PUMP, SYRINGE TYPE CARTRIDGE, STERILE, EACH

K0601 REPLACEMENT BATTERY FOR EXTERNAL INFUSION PUMP OWNED BY PATIENT, SILVER OXIDE, 1.5 VOLT, EACH

K0602 REPLACEMENT BATTERY FOR EXTERNAL INFUSION PUMP OWNED BY PATIENT, SILVER OXIDE, 3 VOLT, EACH

K0603 REPLACEMENT BATTERY FOR EXTERNAL INFUSION PUMP OWNED BY PATIENT, ALKALINE, 1.5 VOLT, EACH

K0604 REPLACEMENT BATTERY FOR EXTERNAL INFUSION PUMP OWNED BY PATIENT, LITHIUM, 3.6 VOLT, EACH

K0605 REPLACEMENT BATTERY FOR EXTERNAL INFUSION PUMP OWNED BY PATIENT, LITHIUM, 4.5 VOLT, EACH

### **DRUGS**

J0133 INJECTION, ACYCLOVIR, 5 MG

J0285 INJECTION, AMPHOTERICIN B, 50 MG

J0287 INJECTION, AMPHOTERICIN B LIPID COMPLEX, 10 MG

J0288 INJECTION, AMPHOTERICIN B CHOLESTERYL SULFATE COMPLEX, 10 MG

J0289 INJECTION, AMPHOTERICIN B LIPOSOME, 10 MG

J0895 INJECTION, DEFEROXAMINE MESYLATE, 500 MG

J1170 INJECTION, HYDROMORPHONE, UP TO 4 MG

J1250 INJECTION, DOBUTAMINE HYDROCHLORIDE, PER 250 MG

J1265 INJECTION, DOPAMINE HCL, 40 MG

J1325 INJECTION, EPOPROSTENOL, 0.5 MG

J1455 INJECTION, FOSCARNET SODIUM, PER 1000 MG

J1457 INJECTION, GALLIUM NITRATE, 1 MG

J1562 INJECTION, IMMUNE GLOBULIN, SUBCUTANEOUS, 100 MG

J1570 INJECTION, GANCICLOVIR SODIUM, 500 MG

J1817 INSULIN FOR ADMINISTRATION THROUGH DME (I.E., INSULIN PUMP) PER 50 UNITS

J2175 INJECTION, MEPERIDINE HYDROCHLORIDE, PER 100 MG

J2260 INJECTION, MILRINONE LACTATE, 5 MG

J2270 INJECTION, MORPHINE SULFATE, UP TO 10 MG

J2271 INJECTION, MORPHINE SULFATE, 100MG

J2275 INJECTION, MORPHINE SULFATE (PRESERVATIVE-FREE STERILE SOLUTION), PER 10 MG

J2278 INJECTION, ZICONOTIDE, 1 MICROGRAM

J3010 INJECTION, FENTANYL CITRATE, 0.1 MG

J3285 INJECTION, TREPROSTINIL, 1 MG

J7799 NOC DRUGS, OTHER THAN INHALATION DRUGS, ADMINISTERED THROUGH DME

J9000 DOXORUBICIN HCL, 10 MG

J9040 BLEOMYCIN SULFATE, 15 UNITS

J9065 INJECTION, CLADRIBINE, PER 1 MG

J9100 CYTARABINE, 100 MG

J9110 CYTARABINE, 500 MG

J9190 FLUOROURACIL, 500 MG

J9200 FLOXURIDINE, 500 MG

J9360 VINBLASTINE SULFATE, 1 MG

J9370 VINCRISTINE SULFATE, 1 MG

J9375 VINCRISTINE SULFATE, 2 MG

J9380 VINCRISTINE SULFATE, 5 MG

### **ICD-9 Codes that Support Medical Necessity**

**The presence of an ICD-9 code listed in this section is not sufficient by itself to assure coverage. Refer to the section on "Indications and Limitations of Coverage and/or Medical Necessity" for other coverage criteria and payment information.**

**For HCPCS codes E0784, J1817:**

[250.00](#) - DIABETES MELLITUS WITHOUT MENTION OF COMPLICATION, TYPE II  
[250.93](#) OR UNSPECIFIED TYPE, NOT STATED AS UNCONTROLLED - DIABETES WITH UNSPECIFIED COMPLICATION, TYPE I [JUVENILE TYPE], UNCONTROLLED

**For HCPCS code J1457:**

275.42 HYPERCALCEMIA

**For HCPCS code J1562:**

279.04 CONGENITAL HYPOGAMMAGLOBULINEMIA

279.05 IMMUNODEFICIENCY WITH INCREASED IGM

279.06 COMMON VARIABLE IMMUNODEFICIENCY

279.12 WISKOTT-ALDRICH SYNDROME

279.2 COMBINED IMMUNITY DEFICIENCY

### **Diagnoses that Support Medical Necessity**

For the specific HCPCS codes indicated above, refer to the previous section.

For all other HCPCS codes, diagnoses are not specified.

### **ICD-9 Codes that DO NOT Support Medical Necessity**

**For the specific HCPCS codes indicated above, all ICD-9 codes that are not specified in the previous section.**

**For all other HCPCS codes, ICD-9 codes are not specified.**

### **ICD-9 Codes that DO NOT Support Medical Necessity Asterisk Explanation**

### **Diagnoses that DO NOT Support Medical Necessity**

For the specific HCPCS codes indicated above, all diagnoses that are not specified in the previous section.

For all other HCPCS codes, diagnoses are not specified.

## **General Information**

### **Documentation Requirements**

Section 1833(e) of the Social Security Act precludes payment to any provider of services unless "there has been furnished such information as may be necessary in order to determine the amounts due such provider" (42 U.S.C. section 13951(e)). It is expected that the patient's medical records will reflect the need for the care provided. The patient's medical records include the physician's office records, hospital records, nursing home records, home health agency records, records from other healthcare professionals and test reports. This documentation must be available upon request.

An order for each item billed must be signed and dated by the treating physician, kept on file by the supplier, and made available upon request. Items billed before a signed and dated order has been received by the supplier must be submitted with an EY modifier added to each affected HCPCS code.

A DME Information Form (DIF) which has been completed, signed, and dated by the supplier, must be kept on file by the supplier and made available upon request. The DIF for External Infusion Pumps is CMS Form 10125. The initial claim must include an electronic copy of the DIF.

For external insulin infusion pumps, an ICD-9 diagnosis code (specific to the 5th digit), describing the condition which necessitates the pump, must be included on each claim.

If a patient begins using an infusion for one drug and subsequently the drug is changed or another drug is added, a Revised DIF must be submitted for use of the pump with the new or additional drug. In the case of an additional drug, all drugs for which the pump is used should be included on the Revised DIF.

For all claims for external insulin infusion pumps, insulin, and/or supplies, if the results of the patient's C-peptide level meet the requirements outlined in section IV of the Coverage and Payment Rules, a KX modifier should be added to the HCPCS code.

If information on an inotropic drug is requested, the supplier should submit a copy of the order and documentation from the treating physician, which includes information relating to each of the criteria (D1-D8) defined in the Indications and Limitations of Coverage section. This must include the before and after inotropic drug infusion values defined in D3. A suggested form for collecting this information is attached.

Questions pertaining to medical necessity on any form used to collect this information may not be completed by the supplier or by anyone in a financial relationship with the supplier. If coverage criteria stated in the policy are not met, the claim should be accompanied by a copy of a letter from the physician giving details of the patient's

history (e.g., dates of past hospitalization for heart failure, prior use of parenteral inotropic and the results, etc.). If invasive hemodynamic studies or impedance cardiography were not performed, the claim should be accompanied by a letter from the attending physician explaining the rationale for not performing the tests and accompanied by any other documentation deemed appropriate to explain this exception.

If additional information on epoprostenol or treprostinil is requested, the supplier should submit signed and dated information from the treating physician stating the patient's diagnosis, the patient's current symptoms caused by pulmonary hypertension, and date and results of the pulmonary artery pressure. There must be a statement that the pulmonary hypertension is not secondary to pulmonary venous hypertension or a disorder of the respiratory system. There must be a statement of whether oral calcium channel blocking agents were tried and if so, the results, and if not, why a trial was not conducted.

For all claims for liposomal amphotericin B (J0287, J0288, J0289), that meet the requirements outlined in section V(C) of the Indications and Limitations of Coverage section, a KX modifier should be added to the HCPCS code

Refer to the Supplier Manual for more information on documentation requirements.

## **Appendices**

### **Utilization Guidelines**

Refer to Indications and Limitations of Coverage and/or Medical Necessity.

### **Sources of Information and Basis for Decision**

Reserved for future use.

### **Advisory Committee Meeting Notes**

### **Start Date of Comment Period**

04/16/1993

### **End Date of Comment Period**

05/31/1993

### **Start Date of Notice Period**

08/01/1993

### **Revision History Number**

EIP020

### **Revision History Explanation**

Revision Effective Date: 01/01/2007

INDICATIONS AND LIMITATIONS OF COVERAGE:

Added clarification about subcutaneous immune globulin.

Revised liposomal amphotericin B LCD statement

HCPCS CODES:

Added: J1562

Revised: A4306

ICD-9 CODES THAT SUPPORT MEDICAL NECESSITY:

Replaced J7799 with J1562

DOCUMENTATION REQUIREMENTS:

Removed CMN requirements.

Added DIF instructions.

Added KX modifier for liposomal amphotericin B.

Removed DMERC references

Revision effective date: 03/01/2006

INDICATIONS AND LIMITATIONS OF COVERAGE:

Added subcutaneous immune globulin (J7799) criteria

ICD-9 CODES THAT SUPPORT MEDICAL NECESSITY:

Added subcutaneous immune globulin and related diagnosis codes.

03/01/2006 - In accordance with Section 911 of the Medicare Modernization Act of 2003, this policy was transitioned to DME PSC TriCenturion (77011) from DMERC Tricenturion (77011).

Revision effective date: 01/01/2006

INDICATIONS AND LIMITATIONS OF COVERAGE:

Added J2278 criteria

HCPCS CODES AND MODIFIERS:

Added J0133, J1265, J2278, J3285

Deleted E0782, Q4075, Q4076, Q4077

Revision effective date: 04/01/2005

HCPCS CODES AND MODIFIERS:

Added: A4223, J1457

Revised: A4222

INDICATIONS AND LIMITATIONS OF COVERAGE:

Added intravenous use for treprostinil.

Added J1457 for gallium nitrate.

Updated insulin pumps with revised NCD criteria.

DOCUMENTATION REQUIREMENTS:

Revised requirements that additional documentation had to be routinely submitted with claims for certain drugs.

Revision effective date: 7/01/2004

LMRP Converted to LCD and Policy Article

INDICATIONS AND LIMITATIONS OF COVERAGE:

Added gallium nitrate to list of covered drugs (F) for cancer related hypercalcemia

Revision effective date: 10/01/2003

HCPCS CODES AND MODIFIERS:

Added: Q4075, Q4076, Q4077

Discontinued: J0286

CODING GUIDELINES: Removed instructions for treprostinil

Revision effective date: 04/01/2003

**HCPCS CODES AND MODIFIERS:**

Added: EY modifier , J0287, J0288, J0289, J1817, K0552, K0601, K0602, K0603, K0604, K0605

Discontinued: A4232, A4632, J1820, K0548

Revised: K0455

**INDICATIONS AND LIMITATIONS OF COVERAGE:**

Added treprostinil to list of covered drugs for pulmonary hypertension. . Adds standard language concerning coverage of items without an order.

**CODING GUIDELINES:**

Adds instructions for treprostinil. Clarifies coding of A4222. Adds guidelines for K0552.

**DOCUMENTATION REQUIREMENTS:**

Adds standard language concerning use of EY modifier for items without an order

The revision dates listed below are the dates the revisions were published and not necessarily the effective dates for the revisions.

04/01/2002 - C-peptide level minimum raised to less than or equal to 110% of lower limit of normal of laboratory's measurement method. HCPCS code K0548 added for insulin lispro. Expanded allowable dosage range for dopamine (less than or equal to 5 mcg/kg/min). Replaced ZX with KX modifier.

12/01/2000 – Incorporated allowance for the use of either invasive hemodynamic monitoring or thoracic electrical bioimpedance, also known as impedance cardiography, in order to qualify a patient for Medicare coverage of inotropic drugs in the treatment of congestive heart failure.

10/01/2000 - Revised coverage criteria for epoprostenol (Flolan®), effective for claims with dates of service on or after October 1, 2000.

04/01/2000 – Incorporated new HCPCS codes that became effective January 1, 2000. In addition, the coverage criteria for liposomal amphotericin B were corrected to consider coverage in patients with impaired renal function rather than impaired hepatic function. Included new coverage criteria for external insulin infusion pumps (HCPCS code E0784) as a result of a revised national coverage determination for section 60-14 of the Coverage Issues Manual. As outlined in the LMRP, external insulin infusion pumps and supplies are covered for type 1 diabetics (only) who meet Medicare coverage criteria. An ICD-9-CM code specific to the fifth digit (e.g., 250.11), describing the condition which necessitates the insulin pump, must be included on all claims for insulin pumps, insulin and/or supplies. Submission of a claim lacking a covered ICD-9-CM diagnosis code will result in a denial for medical necessity. Alternatively, failure to provide an ICD-9-CM diagnosis code on the claim will result in rejection of the claim for missing information. Supplies for the insulin pump should be billed using codes A4221 and A4232. Insulin for use in the pump is billed using code J1820. Codes A4230 (infusion set for external insulin pump, non-needle cannula type) and A4231 (infusion set for external insulin pump, needle type) are not valid for claim submission to the DMERC because they are included in code A4221.

09/01/1999 – Typo corrected from digitoxin to digoxin.

06/01/1999 – Added HCPCS codes (J0285 crosswalk from K0453, J0286, J2271).

General "Reasonable and Necessary" criteria were added to the beginning of the "Coverage and Payment Rules" section. The first part of "Coverage and Payment Rules" was reformatted to improve readability. Changes in the numbering scheme and the addition of bullets and references in the text are intended to improve clarity and interpretation of eligibility criteria. Coverage of liposomal amphotericin B (J0286) was added. This code became effective January 1, 1999, and is covered for patients who have had significant toxicity to standard amphotericin and are unable to complete that course of therapy or for those patients who have significantly impaired hepatic function. An indication for use of epoprostenol (Flolan®)(Code J1325) was added. Effective for dates of service on or after February 1, 1999, J1325 will be covered for those patients with pulmonary hypertension secondary to a connective tissue disease.

03/01/1998 – Crosswalked HCPCS codes K0110 and K0111 to A4221 and A4222. Added HCPCS code K0455. Code J9010 crosswalked to J9000. Added criteria E in Coverage and Payment Rules section regarding parenteral epoprostenol. Added language regarding entities licensed to dispense drugs.

12/01/1997 – Clerical correction.

10/01/1996 – Removed HCPCS J3370 and XX009. Removed vancomycin (not covered effective 9/1/96) in criteria C in Coverage and Payment Rules section. Removed Related Clinical Information section. Added effective date for code J1250 in Coding Guidelines section.

04/01/1996 – Added code K0417. Added effective dates for codes K0417, XX009, and J1250 in Coding Guidelines section.

01/01/1996 – Added codes A9270, J1250, J1455, J1570, J2175, J2260, J3010, J9010, J9110, J9375, & J9380. Added definition for code K0284. Revised Coverage and Payment Rules section. Added Related Clinical Information section. Revised Coding Guidelines and Documentation section.

10/01/1995 – Added codes K0284, J2275 & J9065.

12/01/1993 – Revised description for J1170. Added code J3370 & XX009.

#### **Last Reviewed On Date**

#### **Related Documents**

##### **Article(s)**

A19713 - External Infusion Pumps - Policy Article - Effective January 2007

#### **LCD Attachments**

[Home Parenteral Inotropic Therapy: Data Collection Form](#)  
[External Infusion Pump DIF](#)

**Article for External Infusion Pumps - Policy Article - Effective January 2007 (A19713)**

**Contractor Information**

**Contractor Name**

TriCenturion

**Contractor Number**

77011

**Contractor Type**

DME PSC

**DME MAC this DME PSC is affiliated with**

AdminaStar Federal, Inc., National Heritage Insurance Co.

**Article Information**

**Article ID Number**

A19713

**Article Type**

Article

**Key Article**

Yes

**Article Title**

External Infusion Pumps - Policy Article - Effective January 2007

**Primary Geographic Jurisdiction**

Connecticut  
District of Columbia  
Delaware  
Illinois  
Indiana  
Kentucky  
Massachusetts  
Maryland  
Maine  
Michigan  
Minnesota  
New Hampshire  
New Jersey

New York - Entire State  
Ohio  
Pennsylvania  
Rhode Island  
Virginia  
Vermont  
Wisconsin  
West Virginia

### **DME Region Article Covers**

Jurisdiction A/B

### **Original Article Effective Date**

06/01/2004

### **Article Revision Effective Date**

01/01/2007

### **Article Text**

## **NON-MEDICAL NECESSITY COVERAGE AND PAYMENT RULES**

Injectable drugs administered in a physician's office, whether with or without a pump, must be billed to the local carrier and not the DME MAC. Drugs put into an infusion pump in the physician's office for use in the patient's home must be billed to the DME MAC if the pump is billed to the DME MAC.

Disposable drug delivery systems, including elastomeric infusion pumps (A4305, A4306) are non-covered devices because they do not meet the Medicare definition of durable medical equipment. Drugs and supplies used with disposable drug delivery systems are also non-covered items.

Catheter insertion devices for use with external insulin infusion pump infusion cannulas are included in the allowance for code A4221 and are not separately payable.

The DME MACs do not process claims for implantable infusion pumps (E0782, E0783, E0785, E0786) or drugs and supplies used in conjunction with an implantable infusion pump. Claims for these items must be submitted to the local carrier.

Replacement batteries (K0601-K0605) are not separately payable when billed with a rented infusion pump.

## **CODING GUIDELINES**

An ambulatory infusion pump (E0781) is an electrical or battery operated device, which is used to deliver solutions containing a parenteral drug under pressure at a regulated flow rate. It is small, portable, and designed to be carried by the patient.

A stationary infusion pump (E0791) is an electrical device, which serves the same purpose as an ambulatory pump but is larger and typically mounted on a pole.

A disposable drug delivery system (A4305, A4306) is a device used to deliver solutions containing parenteral drugs under pressure generated from the elastic properties of the container. It is commonly called an elastomeric infusion pump.

An infusion controller (E1399) is an electrical device, which regulates the flow of parenteral solutions under gravity pressure.

A reusable mechanical infusion pump (E0779) is a device used to deliver solutions containing parenteral drugs under pressure at a constant flow rate determined by the tubing with which it is used. It is small, portable, and designed to be carried by the patient. It must be capable of a single infusion cycle of at least 8 hours.

Code E0780 describes a mechanical infusion pump which is similar to an E0779 pump, but which is only capable of a single infusion cycle of less than 8 hours.

Code K0455 describes an ambulatory electrical infusion pump, which is used for the administration of epoprostenol.

Code A4221 includes dressings for the catheter site and flush solutions not directly related to drug infusion. The catheter site may be a peripheral intravenous line, a peripherally inserted central catheter (PICC), a centrally inserted intravenous line with either an external or a subcutaneous port, or an epidural catheter. Code A4221 also includes all cannulas, needles, dressings and infusion supplies (excluding the insulin reservoir) related to continuous subcutaneous insulin infusion via external insulin infusion pump (E0784) and the infusion sets and dressings related to subcutaneous immune globulin administration. Billing for more than 1 unit of service per week is incorrect use of the code and will be denied accordingly.

Code A4222 includes the cassette or bag, diluting solutions, tubing and other administration supplies, port cap changes, compounding charges, and preparation charges. This code is not used for a syringe-type reservoir.

Code K0552 describes a syringe-type reservoir that is used with the external insulin infusion pump (E0784) or with a K0455 pump when it is used to administer treprostinil, or with an E0780 pump used to administer subcutaneous immune globulin. The reservoir may be either glass or plastic and includes the needle for drawing up the drug. This code does not include the drug for use in the reservoir. Code A4232 is invalid for submission to Medicare and should not be used for this purpose.

All supplies (including dressings) used in conjunction with a durable infusion pump (E0779, E0780, E0781, E0784, E0791, K0455) are billed with (1) codes A4221 and A4222 or (2) codes A4221 and K0552. Other codes should not be used for the separate billing of these supplies. Codes A4230 (infusion set for external insulin pump, non-needle cannulas type) and A4231 (infusion set for external insulin pump, needle type) are not valid for claim submission to the DME MAC because they are included in code A4221.

Use A4223 for infusion supplies not used with a covered external infusion pump.

Drugs used in a durable external infusion pump must be coded using the appropriate HCPCS codes. If the drug does not have a distinct code, then use the unclassified drug

code J7799. Do not use code J9999 - this code is not valid for claims billed to the DME MAC.

An infusion drug not administered using a durable infusion pump must be billed using the appropriate HCPCS code plus the GY modifier. If the drug does not have a unique code, use the unclassified drug code, J3490.

Use code J2275 only for morphine sulfate that is labeled "preservative free." Morphine sulfate that is not labeled "preservative free" must be coded J2270 or J2271.

Use code J1817 for insulin administered through an external insulin pump (E0784).

Suppliers should contact the Statistical Analysis Durable Medical Equipment Regional Carrier (SADMERC) for guidance on the correct coding of these items.

### **Coverage Topic**

Durable Medical Equipment  
Prescription Drugs

## **Coding Information**

**No Coding Information has been entered in this section of the article.**

## **Other Information**

### **Revision History Explanation**

Revision effective date: 01/01/2007

NON-MEDICAL NECESSITY COVERAGE AND PAYMENT RULES:

Revised DMERC references to reflect change to DME MAC.

CODING GUIDELINES:

Revised DMERC references to reflect change to DME MAC.

Corrected subcutaneous immunoglobulin code to E0780 in paragraph that addresses K0552.

Removed coding guideline for disposable drug delivery systems with flow rates of 5-50 ml/hour

Revision effective date: 03/01/2006 (June publication)

CODING GUIDELINES:

Added instructions for billing E0779, A4221, and K0552 for subcutaneous immune globulin administration.

03/01/2006 - In accordance with Section 911 of the Medicare Modernization Act of 2003, this article was transitioned to DME PSC TriCenturion (77011) from DMERC Tricenturion (77011).

Revision effective date: 01/01/2006  
NON-MEDICAL NECESSITY COVERAGE AND PAYMENT RULES;  
Corrected error in implantable pump codes.  
Added bundling statement about batteries.  
CODING GUIDELINES:  
Added statement about A4232.

Revision effective date: 04/01/2005  
CODING GUIDELINES:  
Added A4223

Revision Effective Date: 07/01/2004  
LMRP Converted to LCD and Policy Article

### **Related Documents**

#### **LCD(s)**

L5044 - External Infusion Pumps