
Local Medical Review Policies (LMRPs)

14.27 External Infusion Pumps

HCPCS Codes

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

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
- E0782 Infusion pump, implantable, non-programmable
- 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 administration of epoprostenol

Supplies

- A4221 Supplies for maintenance of drug infusion catheter, per week, (list drug separately)
- A4222 Supplies for external drug infusion pump, per cassette or bag (list drug separately)
- A4232 Syringe with needle for external insulin pump, sterile, 3 cc
- A4305 Disposable drug delivery system, flow rate of 50 ml or greater per hour
- A4306 Disposable drug delivery system, flow rate of 5 ml or less per hour
- A9270 Non-covered item or service

Drugs

- J0285 Injection, amphotericin B, 50 mg
- J0286 Injection, amphotericin B, any lipid formulation, 50 mg
- J0895 Injection, deferoxamine mesylate, 500 mg per 5 cc
- J1170 Injection, hydromorphone, up to 4 mg
- J1250 Injection, dobutamine hydrochloride, per 250 mg
- J1325 Injection, epoprostenol, 0.5 mg
- J1455 Injection, foscarnet sodium, per 1000 mg
- J1570 Injection, ganciclovir sodium, 500 mg
- J1820 Injection, insulin, up to 100 units

- J2175 Injection, meperidine hydrochloride, per 100 mg
- J2260 Injection, milrinone lactate, per 5 ml
- J2270 Injection, morphine sulfate, up to 10 mg
- J2271 Injection, morphine sulfate, 100 mg
- J2275 Injection, morphine sulfate (preservative-free sterile solution), per 10 mg
- J3010 Injection, fentanyl citrate, up to 2 ml
- 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
- K0548 Injection, insulin lispro, up to 50 units

HCPCS Modifiers

- GY Item or service statutorily excluded or does not meet the definition of any Medicare benefit
- KX Specific required documentation on file

Benefit Category

Durable Medical Equipment

Reference

Coverage Issues Manual 60-14

Definitions

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).

Code A4222 includes the cassette or bag, diluting solutions, tubing and other administration supplies, port cap changes, compounding charges, and preparation charges.

Code A4232 describes the insulin reservoir for use with the external insulin infusion pump (E0784). The reservoir may be either glass or plastic and includes the needle for drawing up the insulin. This code does not include the insulin for use in the reservoir.

Coverage and Payment Rules

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, "reasonable and necessary" are defined by the following coverage and payment rules.

An external infusion pump is covered for the following indications:

- 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), which has been documented by a fasting serum C-peptide level that is less than or equal to (\leq) 110 percent of the lower limit of normal of the laboratory's measurement method, if either of the following criteria (1) or (2) are met
 1. 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 (a - e) while on the multiple injection regimen:

- a. Glycosylated hemoglobin level (HbA_{1c}) > 7%
 - b. History of recurring hypoglycemia
 - c. Wide fluctuations in blood glucose before mealtime
 - d. Dawn phenomenon with fasting blood sugars frequently exceeding 200 mg/dL
 - e. History of severe glycemic excursions
2. 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.

For patients who have obtained an external insulin infusion pump that was not eligible for reimbursement by Medicare prior to January 1, 2002, insulin and supplies used with the pump are covered for dates of service on or after January 1, 2002 provided the patient has a fasting C-peptide such that the test result is less than or equal to (\leq) 110 percent of the lower limit of normal of the laboratory's measurement method.

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 dietitians who are knowledgeable in the use of continuous subcutaneous insulin infusion therapy.

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

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

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, American Medical Association's Drug Evaluations, 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) - (E):

- 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 (J0286) is 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.

Payment for the liposomal form will be based on the allowance for the least costly medically appropriate alternative, standard amphotericin B (J0285), unless accompanied by a statement from the physician substantiating the medical need for the liposomal form of amphotericin B for a particular patient.

- 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 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 - - ≤ 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 parenteral epoprostenol 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.

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.

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

Medicare only pays for one pump for administering epoprostenol (K0455); 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.

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.

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. More than one unit of service per week is not separately allowed.

Supplies used with an external infusion pump (excluding external insulin infusion pumps - see below), A4222, are covered during the period of covered use of an infusion pump. Allowance is based on the number of cassettes or bags prepared. 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 or bag should be maximized to result in the fewest cassettes or bags 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 A4232. 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.

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.

The DMERC does not process claims for implantable infusion pumps or drugs and supplies used in conjunction with an implantable infusion pump. Claims for these items must be submitted to the local carrier.

Coding Guidelines

Supplies (including dressings) used in conjunction with a durable infusion pump (E0779, E0780, E0781, E0791, K0455) but excluding external insulin infusion pumps (E0784) are included in codes A4221 and A4222. Other codes should not be used for the separate billing of these supplies.

Supplies (including dressings) used in conjunction with an external insulin infusion pump (E0784) are included in codes A4221 and A4232. Other codes, including code A4222, should not be used for the separate billing of these supplies. 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.

Drugs used in a durable 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 DMERC.

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.

For disposable drug delivery systems (e.g., elastomeric) with a flow rate of more than 5 ml per hour and less than 50 ml per hour, use code A9270.

Documentation

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. § 1395l(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 to the DMERC upon request.

An order for the item which has been signed and dated by the treating physician and a certificate of medical necessity (CMN) which has been filled out, signed and dated by the treating physician must be kept on file by the supplier. 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 order and CMN for the pump, insulin and/or supplies. The CMN for external infusion pumps is HCFA Form 851.

For external insulin infusion pumps, the ICD-9 diagnosis code (specific to the 5th digit) must be included on each claim for the pump, insulin and/or supplies.

If a patient begins using an infusion for one drug and subsequently the drug is changed or another drug is added, a revised CMN 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 CMN.

For all external infusion pumps (including external insulin infusion pumps), the initial claim must include a copy of the CMN if filed hard copy. If the claim is filed electronically, the information on the CMN must be transcribed exactly into the GU0 record. (See DMEPOS National Standard Format Matrix for details.) If additional medical necessity information is included, it must be transcribed into the HA0 record.

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 an inotropic drug is ordered, the initial claim must include a copy of the order (prescription and documentation from the treating physician) which includes information relating to each of the criteria (D1-D8) defined in the Coverage and Payment Rules 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 inotropics 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 accompanied by any other documentation deemed appropriate to explain this exception.

If epoprostenol is ordered, the initial claim must include 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.

If the liposomal form of amphotericin B is ordered, the initial claim for J0286 must be submitted with a statement from the physician indicating why the liposomal form of amphotericin B is needed for a particular patient. This documentation should be attached to a hard copy claim or entered into the HAO record of an electronic claim.

Refer to the Supplier Manual for further information on orders, CMNs, medical records and supplier documentation.

Effective Date

Claims with dates of service on or after July 1, 2002.

This is a revision to a previously published policy.

Home Parenteral Inotropic Therapy: Data Collection Form

Patient's Name: _____ HIC #: _____

Information below may not be completed by the supplier nor anyone in a financial relationship with the supplier.

- 1) Results of invasive hemodynamic monitoring or impedance cardiography:

	Cardiac Index	Wedge Pressure	Date
Before inotrope infusion	_____	_____	
On inotrope infusion	_____	_____	_____
Drug _____	Dose _____	mcg/kg/min	

- 2) Cardiac drugs (digoxin, diuretics, vasodilators) immediately prior to inotrope infusion (list name, dose, frequency): _____

- 3) Does this represent maximum tolerated doses of these drugs?

4) Breathing status (check one <u>in each column</u>):	Prior to inotrope infusion	At time of discharge
No dyspnea on exertion	_____	_____
Dyspnea on moderate exertion	_____	_____
Dyspnea on mild exertion	_____	_____
Dyspnea at rest	_____	_____

- 5) Initial home prescription: Drug _____ mcg/kg/min
-
- _____ hrs/day _____ day/week (or every _____ days)

- 6) If continuous infusion is prescribed, have attempts to discontinue inotrope infusion in the hospital failed? _____

- 7) If intermittent infusion is prescribed, have there been repeated hospitalizations for heart failure during which parenteral inotropes were required? _____

- 8) Is the patient capable of going to the physician for outpatient evaluation: _____

- 9) Is routine electrocardiographic monitoring required in the home? _____

The above statements and any additional explanations included separately are true and accurate and there is documentation present in the patient's medical record to support these statements.

Physician Signature: _____ Date: _____

Physician Name Printed/Typed: _____ UPIN #: _____

Physician Specialty: _____