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Local Coverage Determination (LCD): External Infusion Pumps (L11555)

Contractor Information

Contractor Name
CGS Administrators, LLC opens in new window

Contract Number
18003

Contract Type
DME MAC

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LCD Information

Document Information

LCD ID
L11555

LCD Title
External Infusion Pumps

Jurisdiction
Alabama
Arkansas
Colorado
Florida
Georgia
Louisiana
Mississippi
North Carolina
New Mexico
Oklahoma
Puerto Rico
South Carolina
Tennessee
Texas
Virginia
Virgin Islands
West Virginia

Original Effective Date
For services performed on or after 10/01/1993

Revision Effective Date
For services performed on or after 08/01/2012

Revision Ending Date
N/A

Retirement Date
N/A

Notice Period Start Date
08/01/1993

Notice Period End Date
N/A

Coverage Guidance
Coverage Indications, Limitations, 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 local coverage determination, the criteria for "reasonable and necessary", based on Social Security Act § 1862(a)(1)(A) provisions, 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 reasonable and necessary.

An external infusion pump is covered for the following indications (I-V):

An infusion pump described by codes E0779, E0780, E0781, and E0791 is covered for indications I – III, V(A) – V(D), V(F), and V(G). Coverage of other pumps is addressed under indications IV, V (E), and V (H).

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 beneficiary 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 249.00-250.93) 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 beneficiaries 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 beneficiary 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 beneficiary 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 reasonable and necessary. If criterion C or D is not met, the pump and related accessories, supplies, and insulin will be denied as not reasonable and necessary.

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. In addition, the external insulin infusion pump must be ordered and follow-up care rendered by a physician who manages multiple beneficiaries 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.

Subcutaneous insulin is administered using ambulatory infusion pump E0784. Claims for usage of infusion pumps other than E0784 will be denied as not reasonable and necessary.

V. 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 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 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 beneficiary with intractable pain caused by cancer that 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

D. Administration of parenteral inotropic therapy, using the drugs dobutamine, milrinone and/or dopamine for beneficiaries with congestive heart failure and depressed cardiac function if a beneficiary 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):

      i. Dobutamine - - 2.5-10 mcg/kg/min
      ii. Milrinone - - 0.375-0.750 mcg/kg/min
      iii. 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 beneficiary 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 beneficiary 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 beneficiary’s cardiac symptoms, vital signs, weight, lab values, and response to therapy are routinely assessed and documented in the beneficiary’s medical record.

E. Administration of epoprostenol (J1325) or treprostinil (J3285) for beneficiaries 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 beneficiary 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 beneficiary 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.

Epoprostenol/treprostinil is administered using ambulatory infusion pump K0455. Claims for usage of infusion pumps other than K0455 will be denied as not reasonable and necessary.

F. Gallium nitrate (J1457) is covered for the treatment of symptomatic cancer-related hypercalcemia (ICD-9 275.42). In general, beneficiaries with 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 reasonable and necessary.

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

G. Ziconotide (J2278) is covered for the management of severe chronic pain in beneficiaries 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 (J1559, J1561, J1562, J1569) 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 beneficiary 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.

Only an E0779 infusion pump is covered for the administration of subcutaneous immune globulin. If a different pump is used, it will be denied as not reasonable and necessary.

GENERAL

External infusion pumps and related drugs and supplies will be denied as not reasonable and 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, the beneficiary, 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.

An external infusion pump and related drugs and supplies will be denied as not reasonable and 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 reasonable and necessary.

An IV pole (E0776) is covered only when a stationary infusion pump (E0791) is covered. It is considered not reasonable and 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.

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 for infusion drugs. Drugs and related supplies and equipment billed by a supplier who does not meet these criteria will be denied as not reasonable and necessary.

REFILL REQUIREMENTS

For DMEPOS items and supplies provided on a recurring basis, billing must be based on prospective, not retrospective use. For DMEPOS products that are supplied as refills to the original order, suppliers must contact the beneficiary prior to dispensing the refill and not automatically ship on a pre-determined basis, even if authorized by the beneficiary. This shall be done to ensure that the refilled item remains reasonable and necessary, existing supplies are approaching exhaustion, and to confirm any changes or modifications to the order. Contact with the beneficiary or designee regarding refills must take place no sooner than 14 calendar days prior to the delivery/shipping date. For delivery of refills, the supplier must deliver the DMEPOS product no sooner than 10 calendar days prior to the end of usage for the current product. This is regardless of which delivery method is utilized. (CMS Program Integrity Manual, Internet-Only Manual, CMS Pub. 100-8, Chapter 5, Section 5.2.6).

For all DMEPOS items that are provided on a recurring basis, suppliers are required to have contact with the beneficiary or caregiver/designee prior to dispensing a new supply of items. Suppliers must not deliver refills without a refill request from a beneficiary. Items delivered without a valid, documented refill request will be denied as not reasonable and necessary.

Suppliers must not dispense a quantity of supplies exceeding a beneficiary's expected utilization. Suppliers must stay attuned to changed or atypical utilization patterns on the part of their clients. Suppliers must verify with the ordering physicians that any changed or atypical utilization is warranted. Regardless of utilization, a supplier must not dispense more than a three (3)-month quantity at a time.

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Coding Information

Bill Type Codes:

Contractors may specify Bill Types to help providers identify those Bill Types typically used to report this service. Absence of a Bill Type does not guarantee that the policy does not apply to that Bill Type. Complete absence of all Bill Types indicates that coverage is not influenced by Bill Type and the policy should be assumed to apply equally to all claims.

N/A

Revenue Codes:

Contractors may specify Revenue Codes to help providers identify those Revenue Codes typically used to report this service. In most instances Revenue Codes are purely advisory; unless specified in the policy services reported under other Revenue Codes are equally subject to this coverage determination. Complete absence of all Revenue Codes indicates that coverage is not influenced by Revenue Code and the policy should be assumed to apply equally to all Revenue Codes.

N/A

CPT/HCPCS Codes

Group 1 Paragraph: 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

GA – Waiver of liability statement issued as required by payer policy, individual case

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

GZ – Item or service expected to be denied as not reasonable and necessary

JB - Adminstered Subcutaneously

KX - Requirements specified in the medical policy have been met

HCPCS CODES:

EQUIPMENT

Group 1 Codes:

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)

Group 2 Paragraph: SUPPLIES

Group 2 Codes:

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

A9274 EXTERNAL AMBULATORY INSULIN DELIVERY SYSTEM, DISPOSABLE, EACH, INCLUDES ALL SUPPLIES AND ACCESSORIES
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

Group 3 Paragraph: DRUGS

Group 3 Codes:
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
J1559 INJECTION, IMMUNE GLOBULIN (HIZENTRA), 100 MG
J1561 INJECTION, IMMUNE GLOBULIN, (GAMUNEX-C/GAMMAKED), NON-LYOPHILIZED (E.G. LIQUID), 500 MG
J1562 INJECTION, IMMUNE GLOBULIN (VIVAGLOBIN), 100 MG
J1569 INJECTION, IMMUNE GLOBULIN, (GAMMAGARD LIQUID), NON-LYOPHILIZED, (E.G. LIQUID), 500 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 INJECTION, DOXORUBICIN HYDROCHLORIDE, 10 MG
J9040 INJECTION, BLEOMYCIN SULFATE, 15 UNITS
J9065 INJECTION, CLADRIBINE, PER 1 MG
J9100 INJECTION, CYTARABINE, 100 MG
J9190 INJECTION, FLUOROURACIL, 500 MG
J9200 INJECTION, FLOXURIDINE, 500 MG
J9360 INJECTION, VINBLASTINE SULFATE, 1 MG
J9370 VINCRISTINE SULFATE, 1 MG

ICD-9 Codes that Support Medical Necessity

Group 1 Paragraph: 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:

Group 1 Codes:

249.00 - 249.91 opens in new window	SECONDARY DIABETES MELLITUS WITHOUT MENTION OF COMPLICATION, NOT STATED AS UNCONTROLLED, OR UNSPECIFIED - SECONDARY DIABETES MELLITUS WITH UNSPECIFIED COMPLICATION, UNCONTROLLED
250.00 - 250.93 opens in new window	DIABETES MELLITUS WITHOUT MENTION OF COMPLICATION, TYPE II OR UNSPECIFIED TYPE, NOT STATED AS UNCONTROLLED - DIABETES WITH UNSPECIFIED COMPLICATION, TYPE I [JUVENILE TYPE], UNCONTROLLED

Group 2 Paragraph: For HCPCS code J1457:

Group 2 Codes:
275.42 HYPERCALCEMIA

Group 3 Paragraph: For HCPCS code J1559, J1561, J1562, J1569

Group 3 Codes:
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

ICD-9 Codes that DO NOT Support Medical Necessity
Paragraph: 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.

N/A

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General Information

Associated 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." It is expected that the beneficiary's medical records will reflect the need for the care provided. The beneficiary'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.

PRESCRIPTION (ORDER) REQUIREMENTS

GENERAL (PIM 5.2.1)

All items billed to Medicare require a prescription. 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 dispensed and/or billed that do not meet these prescription requirements and those below must be submitted with an EY modifier added to each affected HCPCS code.

DISPENSING ORDERS (PIM 5.2.2)

Equipment and supplies may be delivered upon receipt of a dispensing order except for those items that require a written order prior to delivery. A dispensing order may be verbal or written. The supplier must keep a record of the dispensing order on file. It must contain:

- Description of the item
- Beneficiary's name
- Prescribing Physician's name
- Date of the order and the start date, if the start date is different from the date of the order
- Physician signature (if a written order) or supplier signature (if verbal order)

For the "Date of the order" described above, use the date the supplier is contacted by the physician (for verbal orders) or the date entered by the physician (for written dispensing orders).
Signature and date stamps are not allowed. Signatures must comply with the CMS signature requirements outlined in PIM 3.3.2.4.

The dispensing order must be available upon request.

For items that are provided based on a dispensing order, the supplier must obtain a detailed written order before submitting a claim.

DETAILED WRITTEN ORDERS (PIM 5.2.3)

A detailed written order (DWO) is required before billing. Someone other than the ordering physician may produce the DWO. However, the ordering physician must review the content and sign and date the document. It must contain:

- Beneficiary's name
- Physician's name
- Date of the order and the start date, if start date is different from the date of the order
- Detailed description of the item(s) (see below for specific requirements for selected items)
- Physician signature and signature date

For items provided on a periodic basis, including drugs, the written order must include:

- Item(s) to be dispensed
- Dosage or concentration, if applicable
- Route of Administration
- Frequency of use
- Duration of infusion, if applicable
- Quantity to be dispensed

- Number of refills

For the "Date of the order" described above, use the date the supplier is contacted by the physician (for verbal orders) or the date entered by the physician (for written dispensing orders).

Frequency of use information on orders must contain detailed instructions for use and specific amounts to be dispensed. Reimbursement shall be based on the specific utilization amount only. Orders that only state "PRN" or "as needed" utilization estimates for replacement frequency, use, or consumption are not acceptable. (PIM 5.9)

The detailed description in the written order may be either a narrative description or a brand name/model number.

Signature and date stamps are not allowed. Signatures must comply with the CMS signature requirements outlined in PIM 3.3.2.4.

The DWO must be available upon request.

A prescription is not considered as part of the medical record. Medical information intended to demonstrate compliance with coverage criteria may be included on the prescription but must be corroborated by information contained in the medical record.

MEDICAL RECORD INFORMATION

GENERAL (PIM 5.7 -5.9)

The **Indications and Limitations of Coverage and/or Medical Necessity** section of this LCD contains numerous reasonable and necessary (R&N) requirements. The **Nonmedical Necessity Coverage and Payment Rules** section of the related Policy Article contains numerous non-reasonable and necessary, benefit category and statutory requirements that must be met in order for payment to be justified. Suppliers are reminded that:

- Supplier-produced records, even if signed by the ordering physician, and attestation letters (e.g. letters of medical necessity) are deemed not to be part of a medical record for Medicare payment purposes.

- Templates and forms, including CMS Certificates of Medical Necessity, are subject to corroboration with information in the medical record.

Information contained directly in the contemporaneous medical record is the source required to justify payment except as noted elsewhere for prescriptions and CMNs. The medical record is not limited to physician's office records but may include records from hospitals, nursing facilities, home health agencies, other healthcare professionals, etc. (not all-inclusive). Records from suppliers or healthcare professionals with a financial interest in the claim outcome are not considered sufficient by themselves for the purpose of determining that an item is reasonable and necessary.

CONTINUED USE

Continued use describes the ongoing utilization of supplies or a rental item by a beneficiary.

Suppliers are responsible for monitoring utilization of DMEPOS rental items and supplies. No monitoring of purchased items or capped rental items that have converted to a purchase is required. Suppliers must discontinue billing Medicare when rental items or ongoing supply items are no longer being used by the beneficiary.

Beneficiary medical records or supplier records may be used to confirm that a DMEPOS item continues to be used by the beneficiary. Any of the following may serve as documentation that an item submitted for reimbursement continues to be used by the beneficiary:

1. Timely documentation in the beneficiary's medical record showing usage of the item, related option/accessories and supplies

2. Supplier records documenting the request for refill/replacement of supplies in compliance with the Refill Documentation Requirements (This is deemed to be sufficient to document continued use for the base item, as well)

3. Supplier records documenting beneficiary confirmation of continued use of a rental item

Timely documentation is defined as a record in the preceding 12 months unless otherwise specified elsewhere in this policy.

CONTINUED MEDICAL NEED

For all DMEPOS items, the initial justification for medical need is established at the time the item(s) is first ordered; therefore, beneficiary medical records demonstrating that the item is reasonable and necessary are created just prior to, or at the time of, the creation of the initial prescription. For purchased items, initial months of a rental item or for initial months of ongoing supplies or drugs, information justifying reimbursement will come from this initial time period. Entries in the beneficiary's medical record must have been created prior to, or at the time of, the initial DOS to establish whether the initial reimbursement was justified based upon the applicable coverage policy.

For ongoing supplies and rental DME items, in addition to information described above that justifies the initial provision of the item(s) and/or supplies, there must be information in the beneficiary's medical record to support that the item continues to be used by the beneficiary and remains reasonable and necessary. Information used to justify continued medical need must be timely for the DOS under review. Any of the following may serve as documentation justifying continued medical need:

A recent order by the treating physician for refills

A recent change in prescription

A properly completed CMN or DIF with an appropriate length of need specified

Timely documentation in the beneficiary's medical record showing usage of the item

Timely documentation is defined as a record in the preceding 12 months unless otherwise specified elsewhere in the policy.

REFILL DOCUMENTATION (PIM 5.2.5-6)

A routine refill prescription is not needed. A new prescription is needed when:

- There is a change of supplier
- There is a change in the item(s), frequency of use, or amount prescribed
- There is a change in the length of need or a previously established length of need expires
- State law requires a prescription renewal

For items that the beneficiary obtains in-person at a retail store, the signed delivery slip or a copy of the itemized sales receipt is sufficient documentation of a request for refill.

For items that are delivered to the beneficiary, documentation of a request for refill must be either a written document received from the beneficiary or a contemporaneous written record of a phone conversation/contact between the supplier and beneficiary. The refill request must occur and be documented before shipment. A retrospective attestation statement by the supplier or beneficiary is not sufficient. The refill record must include:

- Beneficiary's name or authorized representative if different than the beneficiary
- A description of each item that is being requested
- Date of refill request
- For consumable supplies i.e., those that are used up (e.g., ostomy or urological supplies, surgical dressings, etc.) - The Supplier should assess the quantity of each item that the beneficiary still has remaining, to document that the amount remaining will be nearly exhausted on or about the supply anniversary date.
- For non-consumable supplies i.e., those more durable items that are not used up but may need periodic replacement (e.g., PAP and RAD supplies) - The supplier should assess whether the supplies remain functional, providing replacement (a refill) only when the supply item(s) is no longer able to function. Document the functional condition of the item(s) being refilled in sufficient detail to demonstrate the cause of the dysfunction that necessitates replacement (refill).

This information must be kept on file and be available upon request.

PROOF OF DELIVERY (PIM 4.26, 5.8)

Proof of delivery (POD) is a Supplier Standard and DMEPOS suppliers are required to maintain POD documentation in their files. For medical review purposes, POD serves to assist in determining correct coding and billing information for claims submitted for Medicare reimbursement. Regardless of the method of delivery, the contractor must be able to determine from delivery documentation that the supplier properly coded the item(s), that the item(s) delivered are the same item(s) submitted for Medicare reimbursement and that the item(s) are intended for, and received by, a specific Medicare beneficiary.

Suppliers, their employees, or anyone else having a financial interest in the delivery of the item are prohibited from signing and accepting an item on behalf of a beneficiary (i.e., acting as a designee on behalf of the beneficiary). The signature and date the beneficiary or designee accepted delivery must be legible.

For the purpose of the delivery methods noted below, designee is defined as any person who can sign and accept the delivery of DMEPOS on behalf of the beneficiary.

Proof of delivery documentation must be available to the Medicare contractor on request. All services that do not have appropriate proof of delivery from the supplier will be denied and overpayments will be requested. Suppliers who consistently fail to provide documentation to support their services may be referred to the OIG for imposition of Civil Monetary Penalties or other administrative sanctions.

Suppliers are required to maintain POD documentation in their files. For external infusion pumps and supplies used with these pumps there are two methods of delivery:

1. Delivery directly to the beneficiary or authorized representative
2. Delivery via shipping or delivery service

<u>Method 1—Direct Delivery to the Beneficiary by the Supplier</u>

Suppliers may deliver directly to the beneficiary or the designee. In this case, POD to a beneficiary must be a signed and dated delivery slip. The POD record must include:

- Beneficiary's name
- Delivery address
- Sufficiently detailed description to identify the item(s) being delivered (e.g., brand name, serial number, narrative description)
- Quantity delivered
- Date delivered
- Beneficiary (or designee) signature and date of signature

The date of signature on the delivery slip must be the date that the DMEPOS item was received by the beneficiary or designee. In instances where the supplies are delivered directly by the supplier, the date the beneficiary received the DMEPOS supply must be the date of service on the claim.

Method 2—Delivery via Shipping or Delivery Service Directly to a Beneficiary

If the supplier utilizes a shipping service or mail order, the POD documentation must be a complete record tracking the item(s) from the DMEPOS supplier to the beneficiary. An example of acceptable proof of delivery would include both the supplier's own detailed shipping invoice and the delivery service's tracking information. The supplier's record must be linked to the delivery service record by some clear method like the delivery service's package identification number or supplier's invoice number for the package sent to the beneficiary. The POD record must include:

- Beneficiary's name
- Delivery address
- Delivery service's package identification number, supplier invoice number or alternative method that links the supplier's delivery documents with the delivery service's records.
- Sufficiently detailed description to identify the item(s) being delivered (e.g., brand name, serial number, narrative description)
- Quantity delivered
- Date delivered
- Evidence of delivery

If a supplier utilizes a shipping service or mail order, suppliers must use the shipping date as the date of service on the claim.

Suppliers may also utilize a return postage-paid delivery invoice from the beneficiary or designee as a POD. This type of POD record must contain the information specified above.

POLICY SPECIFIC DOCUMENTATION REQUIREMENTS

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.

If a beneficiary begins using an infusion for one drug and subsequently the drug is changed another drug is added or if the code for a current drug changes, a Revised DIF must be submitted for use of the pump. The additional new or changed drug or the new HCPCS code for the existing drug must be listed along with all other drugs for which the pump is used should be included on the Revised DIF.

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 beneficiary'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 beneficiary's diagnosis, the beneficiary'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.

JB MODIFIER

For all immune globulin (J1559, J1561, J1562, J1569) and associated infusion pump (E0779) claims where the route of administration is subcutaneous, a JB modifier must be added to each HCPCS code. For other methods of administration, no modifier should be added.

KX, GA, GY and GZ MODIFIERS:
For all claims for external insulin infusion pumps (E0784) and insulin (J1817), if the results of the beneficiary's C-peptide level or beta cell autoantibody test meet the requirements outlined in section IV of the Coverage and Payment Rules, a KX modifier should be added to the HCPCS code.

In the situation above describing use of the KX modifier, if all of the coverage criteria have not been met, the GA or GZ modifier must be added to the code. When there is an expectation of a medical necessity denial, suppliers must enter the GA modifier on the claim line if they have obtained a properly executed Advance Beneficiary Notice (ABN) or the GZ modifier if they have not obtained a valid ABN.

Claims lines billed for the above services without a KX, GA, or GZ modifier will be rejected as missing information.

An infusion drug not administered using a durable infusion pump must be billed using the appropriate HCPCS code plus the GY modifier.

Refer to the Supplier Manual for more information on documentation requirements

Appendices

PIM citations above denote references to CMS Program Integrity Manual, Internet Only Manual 100-8

Utilization Guidelines

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

Sources of Information and Basis for Decision
Reserved for future use.

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Revision History Information

Please note: The Revision History information included in this LCD prior to 1/24/2013 will now display with a Revision History Number of "R1" at the bottom of this table. All new Revision History information entries completed on or after 1/24/2013 will display as a row in the Revision History section of the LCD and numbering will begin with "R2".

Revision History Date	Revision History Number	Revision History Explanation	Reason(s) for Change
08/01/2012	R3	Revision Effective Date: 08/01/2012 (May 2013 Publication) COVERAGE INDICATIONS, LIMITATIONS AND/OR MEDICAL NECESSITY: Revised: Refill requirements to 3-month interval consistent with previously published instructions in August 2012 article, "Items Provided on a Recurring Basis and Request for Refill Requirements - Revised - August 2012 "	• Typographical Error

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Associated Documents

Attachments
Home Parenteral Inotropic Therapy: Data Collection Form opens in new window (PDF - 5 KB)
External Infusion Pump DIF opens in new window (PDF - 34 KB)

Related Local Coverage Documents
Article(s)
A20210 - External Infusion Pumps - Policy Article - Effective January 2013 opens in new window

Related National Coverage Documents
N/A

Public Version(s)
Updated on 05/24/2013 with effective dates 08/01/2012 - N/A
Some older versions have been archived. Please visit the MCD Archive Site opens in new window to retrieve them.
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Keywords

N/A
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