



Medicare Part C Medical Coverage Policy

External Infusion Pumps

Origination: January 8, 1990
Review Date: January 18, 2023
Next Review: January, 2025

******This policy applies to all Blue Medicare HMO, Blue Medicare PPO, Blue Medicare Rx members, and members of any third-party Medicare plans supported by Blue Cross NC through administrative or operational services. ******

DESCRIPTION OF PROCEDURE OR SERVICE

An ambulatory infusion pump is an electrical/battery-operated device used to deliver solutions containing a parenteral drug under pressure at a regulated flow. It is small, portable, and designed to be carried by the member.

A stationary infusion pump is an electrical device that serves the same purpose as ambulatory pump but is larger and typically mounted on a pole.

An infusion controller is an electrical device that regulates the flow of parenteral solutions under gravity pressure.

External infusion pumps are considered Durable Medical Equipment.

POLICY STATEMENT

Coverage will be provided for external infusion pumps when it is determined to be medically necessary, as outlined in the below guidelines and medical criteria.

BENEFIT APPLICATION

Please refer to the member's individual Evidence of Coverage (E.O.C.) for benefit determination. Coverage will be approved according to the E.O.C. limitations if the criteria are met.

Coverage decisions will be made in accordance with:

- The Centers for Medicare & Medicaid Services (CMS) national coverage decisions;
- General coverage guidelines included in original Medicare manuals unless superseded by operational policy letters or regulations; and
- Written coverage decisions of local Medicare carriers and intermediaries with jurisdiction for claims in the geographic area in which services are covered.

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Benefit payments are subject to contractual obligations of the Plan. If there is a conflict between the general policy guidelines contained in the Medical Coverage Policy Manual and the terms of the member's particular Evidence of Coverage (E.O.C.), the E.O.C. always governs the determination of benefits.

INDICATIONS FOR COVERAGE:

A. External infusion pumps are commonly used for:

1. Chronic iron overload-administration of deferoxamine
2. Chemotherapy for liver (heptocellular) cancer or colorectal cancer when disease is unresectable or member refuses surgical excision
3. Morphine for intractable pain caused by cancer

B. Insulin Pumps

External Infusion pumps for insulin may be considered medically necessary when the member meets criteria 1 or 2 and 3 or 4.

1. C-peptide testing requirement- must meet criterion a **or** b **and** criterion c:

- a. C-peptide (amino acid chain that connects A and B chains of insulin into proinsulin, the precursor of insulin) level that is less than or equal to 110 percent of the lower limit of normal of the laboratory's measurement method, **or**
- b. For members 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 percent of the lower limit of normal of the laboratory's measurement method; **and**
- c. A fasting blood sugar obtained at the same time as the C-peptide level is less than or equal to 225 mg/dl.

-or

2. Beta cell autoantibody test is positive

-and

3. The member has completed or is scheduled to complete a comprehensive diabetes education program, and

- a. Has been on a program of multiple daily injections of insulin (at least 3 injections per day) with frequent self-adjustments of insulin dosage for at least 6 months prior to initiation of the insulin pump, **and**
- b. Has documented frequency of glucose self-testing an average of at least 4 times a day during the 2 months prior to the initiation of the insulin pump, **and**
- c. Meets one or more of the following criteria while on the multiple daily injection regimen:

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- i. Glycosylated hemoglobin level (HbA1c) >7.0%; if >9 Medical Director must review
- ii. History of recurring hypoglycemia
- iii. Wide fluctuations in blood glucose before mealtime
- iv. Fasting blood sugars frequently exceeding 200mg/dl
- v. History of severe glycemic excursions

-or

4. The member with diabetes has been on a pump prior to enrollment in the Plan and has documented frequency of glucose self-testing an average of at least 4 times per day.

******NOTE-** HCPCS code K0554 became an invalid code effective January 1, 2023 and will now need to be filed using E0784 and E2103. These codes are for an external ambulatory insulin infusion pump, with dose rate adjustment using therapeutic continuous glucose sensing. Coverage for this HCPCS code is only met if the member meets all the coverage criteria for insulin pumps and meets all criteria for a therapeutic Continuous Glucose Monitor (CGM) as outlined in LCD L33822. (See Additional Information about Integrated Pumps under Special Notes Section)

C. External infusion administration of other drugs may be considered medically necessary 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, **AND**
- An infusion pump is necessary to safely administer the drug, **AND**
- The drug is administered by a prolonged infusion of at least 8 hours because of proven improved clinical efficacy, **AND**
- 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, **AND**
- An infusion pump is necessary to safely administer the drug, **AND**
- The drug is administered by intermittent infusion (each episode of infusion lasting less than 8 hours) that does not require the member to return to the physician's office prior to the beginning of each infusion, **AND**

- 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,

D. Coverage for the administration of other drugs, based on criteria set 1 or 2 above, using an external infusion pump is limited to the following situations 1 - 10:

1. Anticancer Chemotherapy

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.

2. Narcotic Analgesics

Administration of **narcotic analgesics** (except meperidine) in place of morphine to a member with intractable pain caused by cancer that has not responded to an adequate oral/transdermal therapeutic regimen and/or cannot tolerate oral/ trans-dermal or transmucosal narcotic analgesics.

3. Antifungal or Antiviral Drugs

Administration of the following **antifungal or antiviral drugs**: acyclovir, foscarnet, amphotericin B, and ganciclovir.

4. Parenteral Inotropic Therapy

Administration of **parenteral inotropic therapy**, using the drugs dobutamine, milrinone and/or dopamine for members with American College of Cardiology Foundation/American Heart Association (ACCF/AHA) Stage D heart failure or New York Heart Association (NYHA) Class IV heart failure are covered if a member meets **all** of the following criteria:

- a. Member remains symptomatic despite optimal guideline directed medical therapy (GDMT) as defined below; **and**
- b. As "Bridge" therapy for members eligible for and awaiting mechanical circulatory support (MCS)/cardiac transplantation, or as palliative care for members not eligible for MCS/cardiac transplantation; **and**
- c. Prescribed following an evaluation by a cardiologist with training in the management of advanced heart failure; **and**
- d. There is documented improvement in the member's symptoms of heart failure while on the selected inotropic drug at the time of discharge from an inpatient or skilled nursing care facility; **and**
- e. An evaluation every 3 months by the prescribing provider or a heart failure team with oversight by a cardiologist which documents the member's cardiac symptoms and the continuing response and need for therapy.

NOTE: Guideline-directed medical therapy (GDMT) is defined as, compliance with optimal medical therapy as defined by ACCF/AHA guideline–recommended therapies (primarily Class I recommendations). These include the use of diuretics, ACE inhibitors or ARB antagonists, beta-blockers, aldosterone antagonists, hydralazine & isosorbide dinitrate, and statins, as appropriate.

For an external infusion pump and related inotropic drugs covered prior to 12/01/2015, if the Medicare coverage criteria in effect on the initial date of service were met, the pump and drug(s) will continue to be covered for dates of service on or after 12/01/2015 as long as the member continues to meet medical necessity. .

5. Epoprostenol

Administration of parenteral poprostenol or subcutaneous treprostinil for members with pulmonary hypertension if they meet the following disease criteria:

- a. 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**
- b. The member 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:
 - i. The pulmonary hypertension has progressed despite maximal medical and/or surgical treatment of the identified condition; **and**
 - ii. The mean pulmonary artery pressure is greater than 25 mm Hg at rest or greater than 30 mm Hg with exertion; **and**
 - iii. The member has significant symptoms from the pulmonary hypertension (i.e., severe dyspnea on exertion, and either fatigability, angina, or syncope); **and**
 - iv. Treatment with oral calcium channel blocking agents has been tried and failed, or has been considered and ruled out.

6. Gallium nitrate

Gallium nitrate is covered for the treatment of symptomatic cancer-related hypercalcemia. In general, members 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 medically necessary. More than one course of treatment for the same episode of hypercalcemia will be denied as not medically necessary.

7. Ziconotide

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

8. Subcutaneous immune globulin

See Medical Coverage Policy for Immunoglobulin Therapy (Intravenous and Subcutaneous) in the Home for coverage criteria:

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 policy.

9. Levodopa-Carbidopa

Enteral suspension is only covered for treatment of motor fluctuations in members with Parkinson's disease (PD), if the following are met:

- a. The member has been evaluated by a neurologist, who prescribes and manages member's treatment; **and**
- b. Idiopathic PD based on the presence of bradykinesia and at least one other cardinal PD feature (tremor, rigidity, postural instability); **and**
- c. L-dopa responsive with clearly defined "On" periods; **and**
- d. Persistent motor complications with disabling "Off" periods for a minimum of 3 hours/day, despite medical therapy with levodopa-carbidopa, **and** at least one other class of anti-PD therapy ie. CMOT inhibitor or MAO-B inhibitor.

10. Blinatumomab

- a. Up to nine (9) cycles for adult and pediatric beneficiaries with relapsed or refractory (R/R) B-cell precursor acute lymphoblastic leukemia (ALL); or
- b. Up to four (4) cycles for adult and pediatric members with relapsed or refractory (R/R) B-cell precursor ALL in first or second remission with minimal residual disease (MRD) greater than or equal to 0.1%.

WHEN COVERAGE WILL NOT BE APPROVED

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External infusion pumps and related drugs and supplies will be denied as not medically necessary when the criteria described above are not met.

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.

If prior authorization is requested for the external infusion pump and the administration of the drug is started in the physician's office, then the pump is incident to the physician's service and should **NOT** be approved.

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

Compounded drugs (J7999) will be denied as not reasonable and necessary.

Special Notes

The only Medicare approved integrated pump is the Tandem pump because the CGM used with this pump is the Dexcom CGM and is billed with E2103 code. All other CGMs are not billed with a Medicare approved code.

BILLING/ CODING/PHYSICIAN DOCUMENTATION INFORMATION

This policy may apply to the following codes. Inclusion of a code in the section does not guarantee reimbursement.

Applicable codes: E0776, E0779, E0780, E0781, E0784, E0791, E2103, A4221, A4222, A4223, K0455, K0552, K0601, K0602, K0603, K0604, K0605, J0133, J0285, J0287, J0288, J0289, J0895, J1170, J1250, J1265, J1325, J1455, J1457, J1555, J1558, J1559, J1561, J1562, J1569, J1570, J1575, J1817, J2175, J2260, J2270, J2274, J2278, J3010, J3285, J7340, J7799, J9000, J9040, J9065, J9100, J9039, J9190, J9200, J9360, J9370, A4305, A4306, A9274, A4602

For drugs being dispensed with the pump, use applicable J codes.

The Plan may request medical records for determination of medical necessity. When medical records are requested, letters of support and/or explanation are often useful but are not sufficient documentation unless all specific information needed to make a medical necessity determination is included.

References:

1. Medicare National Coverage Determination for Infusion Pumps (ID #280.14); Effective date, 12/17/2004, accessed via Internet site www.cms.gov/medicare-coverage-database on 12/18/2012, 1/11/2023.
2. Medicare Local Coverage Determination for External Infusion Pumps – CGS Administrators (L11555); Effective date, 1/1/2015, accessed via www.cms.gov/mcd/viewlcd 2/13/15. (NOTE: This LCD has been retired, keeping as a reference for staff to use when needing to refer to prior criteria of parenteral inotropic therapy for clinical status).
3. Medicare Local Coverage Determination for External Infusion Pumps – CGS Administrators (L33794); Effective date 3/29/18, accessed via www.cms.gov/ on 1/11/2023

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4. CGS: Celerian Group Company News and Publication: Cuvitru–Correct Coding; November 10, 2016. Accessed via internet site <https://cgsmedicare.com/jb/pubs/news/2017/11/cope5337.html> on 1/11/2023.
5. Palmetto GBA: Durable Medical Equipment Coding System (DMECS); January 1, 2023. Accessed via internet site https://www4.palmettogba.com/pdac_dmeacs/searchProductClassificationResults.do?codeDecision=E2103 on 1/11/2023.

Policy Implementation/Update Information:

Revision Date: January 19, 1998; April 26, 1999; December 16, 2002; February 10, 2004

(Policy renamed: External Infusion Pumps on 2/10/2004. Previous policy name “Insulin Pump – External); November 30, 2005

Revision Date: November 28, 2007: Added C-Peptide testing requirement and Beta cell autoantibody test to criteria for coverage;

Added drugs Gallium Nitrate, Ziconotide, and Subcutaneous immune globulin to list of drugs covered in limited situations.

Revision Date: September 2009: No changes proposed to the review criteria. Formatting and minor wording changes only.

Revision Date: November 24, 2010: No changes to review criteria.

Revision Date: December 15, 2010: Updated codes section to remain current with CMS changes that go into effect 1/1/2011; no coverage criteria changes required.

Revision Date: January 16th, 2013. No changes to criteria. Reformatting of language to mirror the LCD.

Revision Date: March 18, 2015, added coverage for Levodopa-Carbidopa enteral suspensions and Blinatumomab, under section D: Coverage for the administration of other drugs, item #9 and 10 based on updated LCD guidelines, updated codes.

Revision Date: November 18, 2015: Indications for Coverage – updated criteria for parenteral inotropic therapy per updated LCD, revised language for item #8 Subcutaneous immune globulin – referencing the IVIG Medical Policy for coverage criteria; When Coverage Will Not Be Approved – added denial for Compound Drugs Q9977; Code section updated per LCD. December 16, 2015 Coding update only.

Revision Date: November 16, 2016. When Coverage will Not be Approved: “If prior authorization is requested for the external infusion pump and the administration of the drug is started in the physician’s office, then the pump is incident to the physician’s service and should not be approved.”

Revision Date: January 18, 2017. Under Subcutaneous Immune Globulin, removed “Only E0779 infusion pump is covered for the administration of subcutaneous immune globulin. If a different pump is requested, it will be denied as not reasonable and necessary.” added “NOTE: There is now a newly covered, FDA approved subcutaneous immune globulin drug called Cuvitru (Shire). It is filed with unlisted code (J7799). Coverage is available when all of the following requirements have been met: The criteria for subcutaneous immune globulin via external infusion pump are met. Under Billing/Coding Added: J157 5.

Revision Date: March 21, 2018; Added New Code to Coding Section and to Special Note: Cuvitru-J1555.

Revision Date: June 20 2018; CMS Update: Updated Indications For Coverage 1. D. Blinatumomab- Up to four (4) cycles for adult and pediatric beneficiaries with relapsed or refractory (R/R) B-cell precursor acute lymphoblastic leukemia (ALL); or Up to two (2) cycles for adults with Philadelphia chromosome negative (Ph-) B-cell precursor ALL in first or second remission with minimal residual disease (MRD) greater than or equal to 0.1%, and who are awaiting an allogeneic hematopoietic stem cell transplantation.

Revision Date: January 16, 2019: Annual Review, Staff Clarification: Indications for Coverage: B. Diabetes heading changed to Insulin Pump. Indications for Coverage D. 8. Removed “NOTE: There is now a newly covered, FDA approved subcutaneous immune globulin drug called Cuvitru (Shire). It now has an assigned code of J1555). Coverage is available when the following requirements have been met: The criteria for subcutaneous immune globulin via external infusion pump are met” Per committee recommendation, also made the word “and” bold within this section to highlight importance of all of the criteria being met.

Revision Date: November 20, 2019; Staff Clarification; removal of “Liposomal amphotericin B preparations are covered for members who meet one of the following criteria: a. The member 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 b. The member has significantly impaired renal function.”

Revision Date: February 19, 2020; CMS Update; Added New Coverage Criteria to Indications for Coverage: B. 4. **NOTE**-HCPCS code E0787 is an external ambulatory insulin infusion pump, with dose rate adjustment using therapeutic continuous glucose sensing. Coverage for this HCPCS code is only met if the member meets all the coverage criteria for insulin pumps and meets all criteria for a therapeutic Continuous Glucose Monitor (CGM) as outlined in LCD L33822. Indications for Coverage: Blinatumomab - updated from 4 to 9 cycles to make consistent with LCD.

Revision Date: May 20, 2020: CMS Update: Addition of newly approved unlisted subcutaneous immunoglobulin drug Xembify (J7799) to LCD. Addition of **NOTE*****There is now a newly approved subcutaneous immune globulin drug called Xembify (J7799) that is administered subcutaneously via an infusion pump. Coverage is available when the following requirements have been met: The criteria for subcutaneous immune globulin via external infusion pump are met. (See Medical Coverage Policy: Immunoglobulin Therapy (Intravenous and Subcutaneous) in the home) to Indications for Coverage A. 2.

Revision Date: October 21, 2020; CMS update; Indications for Coverage B. 4. Note updated to read **NOTE**-HCPCS code E0787 has become an invalid code effective 9/15/2020 and will now need to be filed using E0784 plus K0554. These codes are for an external ambulatory insulin infusion pump, with dose rate adjustment using therapeutic continuous glucose sensing. Coverage for this HCPCS code is only met if the member meets all the coverage criteria for insulin pumps and meets all criteria for a therapeutic Continuous Glucose Monitor (CGM) as outlined in LCD L33822.”

Revision Date: December 16, 2020; Staff Clarification. Under Indications for Coverage B.4. Added: (See Additional Information about Integrated Pumps under Special Notes Section). Added Special Notes: The only Medicare approved integrated pump is the Tandem pump because the CGM used with this pump is the Dexcom CGM and is billed with K0554 code. All other CGMs are not billed with a Medicare approved code.

Revision Date: February 16, 2022; No CMS Updates. Minor Revisions only.

Revision Date: January 18, 2023: CMS Update-LCD was revised to replace CGM HCPCS code K0554 with a new CGM HCPCS code E2103; K0554 removed and E2103 added; Reference #4 updated to reflect updated link; Added an additional reference.

Approval Dates:

External Infusion Pumps

Medical Coverage Policy Committee: January 24, 2023

Policy Owner: Beth Sell, RN, BSN

Medical Policy Coordinator