Medical Policy

Northwood

External Infusion Pump and Supplies

Description

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 an 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.

Policy

An external infusion pump and supplies are considered reasonable and necessary when a member meets coverage criteria.

Policy Guidelines

Medicare Member Coverage Criteria:

Refer to Medicare policy (L33794) and article (A52507) for coverage criteria.

Non-Medicare Member Coverage Criteria:

External infusion pumps are commonly used for:

- Administration of deferoxamine for the treatment of chronic iron overload.
- Chemotherapy for liver (hepatocellular) cancer or colorectal cancer when disease is unresectable, or member refuses surgical excision.
- Morphine for intractable pain caused by cancer.
- Administration of continuous subcutaneous insulin for the treatment of diabetes mellitus **(Refer to Insulin Infusion Pump and Supplies policy).**

External infusion administration of other drugs may be considered reasonable and 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 practitioner'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.

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 - J:

A. 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.

B. Narcotic Analgesics

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

C. Antifungal or Antiviral Drugs

Administration of the following **antifungal or antiviral drugs**: acyclovir, foscarnet, amphotericin B, and ganciclovir. Liposomal amphotericin B preparations are covered for members who meet one of the following criteria:

1. 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**
2. The member has significantly impaired renal function.

D. Parenteral Inotropic Therapy

Administration of **parenteral inotropic therapy**, using the drugs dobutamine, milrinone or dopamine for members with ACCF/AHA Stage D heart failure (HF) or NYHA Class IV HF, if a member meets all of the following criteria:

1. Remains symptomatic despite optimal guideline directed medical therapy GDMT as defined below; and,
2. As "Bridge" therapy for members eligible for and awaiting mechanical circulatory support MCS/ Cardiac transplantation, or as palliative care for members not eligible for either MCS/cardiac transplantation; and
3. Prescribed following an evaluation by a cardiologist with training in the management of advanced heart failure; and
4. There has been a documented improvement in the members symptoms of heart failure while on the selected inotropic drug at the time of discharge from an inpatient or skilled nursing care facility; and
5. An evaluation every three months by the prescribing provider or a heart failure team with oversight by a cardiologist with training in the management of advanced heart failure, which documents the member's cardiac symptoms and the continuing response and need for therapy. The heart failure team or practitioner may have no financial relationship with the supplier.

Guideline-directed medical therapy (GDMT) is 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.

E. Epoprostenol or Treprostinil

Administration of epoprostenol or treprostinil for members 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 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:

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 member 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.

e. 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

Gallium nitrate is covered for the treatment of symptomatic cancer-related hypercalcemia. In general, members with a serum calcium (corrected for albumin) less than 12 mg/dl would not be expected to be symptomatic. The recommended usage for gallium nitrate is daily for five consecutive days. Use for more than 5 days will be denied as not 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

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.

H. Subcutaneous immune globulin

Subcutaneous immune globulin is considered reasonable and necessary if criteria 1-3, and criterions 4 or 5 are met:

1. The subcutaneous immune globulin preparation is a pooled plasma derivative which is FDA approved and,
2. The SCIg is administered in the home; and,
3. The treating practitioner has determined that administration of the SCIg in the members home is medically necessary and appropriate; and,
4. The member has a diagnosis of primary immune deficiency disorder; or
5. The member has a diagnosis of chronic inflammatory demyelinating polyneuropathy that has responded to IVIg treatment. (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.

I. Levodopa-Carbidopa

Levodopa-Carbidopa enteral suspension is only covered for treatment of motor fluctuations in members with Parkinson's disease who meet all of the following criteria:

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

Levodopa-Carbidopa enteral suspension is not reasonable and necessary for members with any of the following:

1. Atypical Parkinson's syndrome or secondary Parkinson's; or,
2. Non-levodopa responsive PD; or,
3. Contraindication to percutaneous endoscopic gastro-jejunal (PEG-J) tube placement or long-term use of a PEG-J.

J. Blinatumomab

Blinatumomab is only covered for:

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

Maximum utilization is 25 vials per month. Claims for more than 25 vials will be denied as not reasonable and necessary.

MISCELLANEOUS:

External infusion pumps and related drugs and supplies will be denied as not reasonable and necessary when the criteria 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 Insurer, the member, 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, E0784, or K0456).

External Infusion Pump and Supplies

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.

Claims for supply HCPCS codes A4224 and A4225 used with an external infusion pump other than HCPCS code E0784 will be denied as incorrect coding.

Supplies for the maintenance of a parenteral drug infusion catheter 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.

Compounded drugs NOC J7999 billed with an external infusion pump will be denied as not reasonable and necessary.

Claims for compounded drugs that do not use code Q9977 or J7999 will be denied as incorrect coding.

HCPCS Code	Description
Group One 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, WITH ADMINISTRATIVE EQUIPMENT, WORN BY PATIENT
E0791	PARENTERAL INFUSION PUMP, STATIONARY, SINGLE OR MULTI-CHANNEL
E1399	DME- MISCELLANEOUS
K0455	INFUSION PUMP USED FOR UNINTERRUPTED PARENTERAL ADMINISTRATION OF MEDICATION, (E.G., EPOPROSTENOL OR TREPROSTINOL).

Group 2 Codes

A4221	SUPPLIES FOR MAINTENANCE OF DRUG INFUSION CATHETER, PER WEEK (LIST DRUGS 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
A4602	REPLACEMENT BATTERY FOR EXTERNAL INFUSION PUMP OWNED BY MEMBER, LITHIUM, 1.5 VOLT, EACH
A9270	NON-COVERED ITEM OR SERVICE
K0552	SUPPLIES FOR EXTERNAL DRUG INFUSION PUMP, SYRINGE TYPE CARTRIDGE, STERILE EACH
K0601	REPLACEMENT BATTERY FOR EXTERNAL INFUSION PUMP OWNED BY MEMBER, SILVER OXIDE, 1.5 VOLT, EACH

K0602	REPLACEMENT BATTERY FOR EXTERNAL INFUSION PUMP OWNED BY MEMBER, SILVER OXIDE, 3 VOLT, EACH
K0603	REPLACEMENT BATTERY FOR EXTERNAL INFUSION PUMP OWNED BY MEMBER, ALKALINE, 1.5 VOLT, EACH
K0604	REPLACEMENT BATTERY FOR EXTERNAL INFUSION PUMP OWNED BY MEMBER, LITHIUM, 3.6 VOLT, EACH
K0605	REPLACEMENT BATTERY FOR EXTERNAL INFUSION PUMP OWNED BY MEMBER, LITHIUM, 4.5 VOLT, EACH

Exclusions

External infusion pumps and related drugs and supplies will be considered not reasonable and necessary when the criteria described above are not met.

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

Disposable drug delivery systems and related supplies, including elastomeric (disposable balloon delivery type) infusion pumps are considered not reasonable and necessary devices because they do not meet the definition of durable medical equipment.

The following items are considered not reasonable and necessary because they are convenience items:

1. Remote Controller
2. Computer software and/or adapter
3. Pump covers, cases including shower bags

Non-Covered HCPCS Codes:

A4244	Alcohol or peroxide, per pint
A4245	Alcohol wipes, per box
A4246	Betadine or pHisoHex solution, per pint
A4247	Betadine or iodine swabs, per box

A5120 Skin barrier wipes or swabs, each (Medicare only)

Documentation Requirements

Items in this policy may be subject to the Affordable Care Act (ACA) 6407.

The Affordable Care Act (ACA) 6407 requires that the treating physician conduct a face-to-face examination during the six-month period preceding the written order. The documentation must be received by the provider prior to delivery for certain DME items. The documentation must describe a medical condition for which the DME is being prescribed.

Important Note:

Northwood's Medical Policies are developed to assist Northwood in administering plan benefits and determining whether a particular DMEPOS product or service is reasonable and necessary. Equipment that is used primarily and customarily for a non-medical purpose is not considered durable medical equipment.

Coverage determinations are made on a case-by-case basis and are subject to all of the terms, conditions, limitations, and exclusions of the member's contract including medical necessity requirements.

The conclusion that a DMEPOS product or service is reasonable and necessary does not constitute coverage. The member's contract defines which DMEPOS product or service is covered, excluded or limited. The policies provide for clearly written, reasonable and current criteria that have been approved by Northwood's Medical Director.

The clinical criteria and medical policies provide guidelines for determining the medical necessity for specific DMEPOS products or services. In all cases, final benefit determinations are based on the applicable contract language. To the extent there are any conflicts between medical policy guidelines and applicable contract language, the contract language prevails. Medical policy is not intended to override the policy that defines the member's benefits, nor is it intended to dictate to providers how to direct care. Northwood Medical policies shall not be interpreted to limit the benefits afforded to Medicare or Medicaid members by law and regulation and Northwood will use the applicable state requirements to determine required quantity limit guidelines.

Medical Policy

External Infusion Pump and Supplies

Northwood's policies do not constitute medical advice. Northwood does not provide or recommend treatment to members. Members should consult with their treating practitioner in connection with diagnosis and treatment decisions.

Northwood follows all CMS National Coverage Determinations (NCD) and Local Coverage Determinations (LCD), as applicable.

References:

Centers for Medicare and Medicaid Services, Medicare Coverage Database, National Coverage Documents; October 2016. Accessed December 20, 2017. Accessed December 14, 2021.

National Government Services, Inc. Jurisdiction A DME MAC, Local Coverage Determination No.L33794; revised date October 1, 2015.

CGS Administrators, LLC. Jurisdiction B DME MAC, Local Coverage Determination No. L33794; Last accessed and reviewed 12-7-23.

Change/Authorization History

Revision Number	Date	Description of Change	Prepared by	Approved by	Review Date:	Effective Date:
A	11-20-06	Initial Release	Rosanne Brugnoni	Ken Fasse	n/a	
01	12-08	Annual Review – no changes	Susan Glomb	Ken Fasse	n/a	
02	12-22-09	Annual Review/ no changes	Susan Glomb	Ken Fasse	Dec.2009	
03	12-02-10	Annual Review – No Changes	Susan Glomb	Ken Fasse	Dec. 2010	
05	07-20-11	Added Important Note to all Medical Policies	Susan Glomb	Dr. B. Almasri		
06	11-23-11	Annual Review. References added to policy.	Susan Glomb	Dr. B. Almasri	Nov. 2011	

07	11-28-12	Annual Review – No changes	Susan Glomb	Dr. B. Almasri	Nov 12	
08	12-30-13	Annual Review- No changes	Susan Glomb	Dr. B. Almasri	Dec 13	
09	11-24-14	Annual Review. Added: Items in this policy may be subject to the Affordable Care Act (ACA) 6407 requirements	Susan Glomb	Dr. B. Almasri		
10	12-30-14	IC only. Code: A4602- Replacement battery for external infusion pump owned by member, lithium, 1.5-volt, ea.	Susan Glomb	Dr. B. Almasri		
11	12-14-15	Annual Review. Updated Medicare reference.	Lisa Wojno	Dr. B. Almasri		
12	12-28-16	Annual Review. Updated policy to reflect Medicare policy.	Susan Glomb	Dr. B. Almasri		
13	12-20-17	Annual review. Per Medicare guidelines, expanded coverage for adult and pediatric patients with relapsed or refractory (R/R) B-cell precursor acute lymphoblastic leukemia (ALL).	Carol Dimech	Dr. C. Lerchin	December 2017	
14	12-3-18	Annual review. No changes.	Carol Dimech	Dr. C. Lerchin	December 2018	
15	12-09-19	Annual review. Updated B-cell precursor acute lymphoblastic leukemia coverage.	Carol Dimech	Dr. C. Lerchin	December 2019	December 2019
16	12-11-20	Annual review. Per CMS, revised “physician” to “practitioner”; added A4224 to group 2 HCPCS code list.	Carol Dimech	Dr. C. Lerchin	December 11, 2020	December 11, 2020
17	12-14-21	Annual Review. Added NCD/LCD verbiage to	Carol Dimech/Susan	Dr. C. Lerchin	December 14, 2021	December 14, 2021

		"Important Note".	Glomb			
18	12-7-22	Annual review. Removed HCPCS code A4224 – refer to insulin infusion pump policy.	Carol Dimech	Dr. C. Lerchin	12-7-22	12-7-22
19	12-7-23	Annual review. No changes.	Carol Dimech	Dr. C. Lerchin	12-7-23	12-7-23