Medical Policy

Insulin Infusion Pump and Supplies

Description

An insulin infusion pump is a battery operated device which is used to deliver insulin at a controlled rate through a needle placed under the skin.

Policy

An insulin pump is **reasonable and necessary** for administration of continuous subcutaneous insulin for the treatment of diabetes mellitus when members meet the coverage criteria below.

Policy Guidelines

Coverage Criteria:

For **Medicare members**:

Administration of continuous subcutaneous insulin for the treatment of diabetes mellitus 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 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 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 member 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 member 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 member 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 members 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.

For **non-Medicare members**

With a diagnosis of diabetes mellitus, the medical record must show documentation of ALL of the following:

a. Completion of a comprehensive diabetes education program
b. A regimen of at least three injections daily with frequent self-adjustments of insulin dose for at least six months prior to the initiation of the pump
c. Frequency of glucose self-testing on average at least four times per day during the two months prior to initiation of the insulin pump
d. At least one of the following while on the multiple daily injection regimen:
    i. Glycosylated hemoglobin level (HbA1c) > 7.0 percent

ii. History of recurring hypoglycemia
iii. Wide fluctuations in blood glucose before mealtime
iv. Dawn phenomenon with fasting blood sugars frequently exceeding 200 mg/dL
v. History of severe glycemic excursions

1. For members who are currently using an insulin infusion pump and have documented frequency of glucose self-testing an average of at least 4 times per day during the month prior.

Continued coverage of an external insulin pump and supplies requires that the member 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 members 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.

Limitations:

1. Repair of an insulin pump is limited to restoration to a serviceable condition.
2. Replacement of an insulin pump will be covered when the cost of repair exceeds the purchase price, or when necessitated by irreparable damage not due to misuse, intentional or non-intentional. **For NH Medicaid members replacement is limited to one pump per recipient every 4 years.**
3. Supplies are limited to the quantities listed below:

HCPCS Code	Description	Pump Model	Quantity
A4230	Infusion set for external insulin pump; non-needle type	Animas	15-25 per month
A4230	Infusion set for external insulin pump; non-needle type	MiniMed	20 per month (Two boxes)
A4231	Infusion set for external insulin pump; needle type	Animas	15-25 per month
A4231	Infusion set for external insulin pump; needle type	MiniMed	30 per month
A6257	Transparent dressing	All models	30 per month
A4649	Piston Rod	All models	1 every 12 months

A4232	Supplies for external infusion pump, syringe type cartridge, sterile, each	Animas	15-25 per month
A4232	Supplies for external infusion pump, syringe type cartridge, sterile, each	MiniMed	24 per month (one box)
K0601	Replacement battery for external infusion pump owned by patient, silver oxide, 1.5v, each	Animas	4 per month
K0601	Replacement battery for external infusion pump owned by patient, silver oxide, 1.5 volt, each	MiniMed	6 per month

Limitations:

1. The following items are considered not reasonable and necessary.
    a. Easy fill filling aid
    b. Remote Controller
    c. Computer software, adapter, and upload kits
    d. Pump covers, cases including shower bags
    e. Infusion set insertion device (Sof-serter, Quick-serter, Sil-serter)

HCPCS Level II Codes and Description

COVERED HCPCS CODES:

A4230	Infusion set for external insulin pump, non-needle cannula type
A4231	Infusion set for external insulin pump, needle type
A6257	Transparent film, 16 sq. inches or less, each dressing
A4649	Surgical supply, miscellaneous (use for batteries, piston rod, adapter)
E0784	External ambulatory infusion pump, insulin
K0552	Supplies for external infusion pump, syringe type cartridge, sterile, each
K0601	Replacement battery for external infusion pump owned by patient, silver oxide, 1.5v, each
K0602	Replacement battery for external infusion pump owned by patient silver oxide, 3volt, 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, alkaline, 3 volt, each
K0605	Replacement battery for external infusion pump owned by patient,

	lithium, 4.5 volt, each
A5120	MEDICAID ONLY. Skin barrier wipes or swabs, each 50ct. every other month.

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)
A9274	External ambulatory insulin delivery system, disposable, each, includes all supplies and accessories. Not reasonable and necessary.

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.

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

References

Cigna: External Insulin Pumps.
http://www.cigna.com/customer_care/healthcare_professional/coverage_positions/medical/mm_0087_coveragepositioncriteria_external_insulin_pumps.pdf

Aetna: Infusion Pumps.
http://www.aetna.com/cpb/medical/data/100_199/0161.html

Centers for Medicare and Medicaid Services, Medicare Coverage Database, National Coverage Documents; October 2015.

Centers for Medicare & Medicaid Services (CMS). Decision memo for insulin pump: C-peptide levels as a criterion for use (CAG-00092R). Baltimore, MD: CMS; Accessed 6/9/2011 from: http://www.cms.gov/mcd/viewdecisionmemo.asp?id=109.

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

National Heritage Insurance Company (NHIC), External Infusion Pumps. Local Coverage Determination No. L5044. Durable Medical Equipment Medicare Administrative Carrier Jurisdiction A. Chico, CA: NHIC; revised February 4, 2011.

Applicable URAC Standard

Core 8	Staff operational tools and support

Change/Authorization History

Revision Number	Date	Description of Change	Prepared by	Approved by	Review 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
04	04-22-11	Added inclusion of Skin barrier wipes for Medicaid members. 50ct. every other month.	Susan Glomb	Dr. Almasri	
05	07-20-11	Added Important Note to all Medical Policies	Susan Glomb	Dr. B. Almasri	

06	11-30-11	Annual Review. Added References to Policy	Susan Glomb	Dr. B. Almasri	Nov. 2011
07	03-28-12	Policy updated to distinguish between criteria for Type 1 diabetics vs. Type 2 diabetics. Cigna reference added to policy.	Susan Glomb	Dr. B. Almasri	March 2012
08	8-29-12	Removed Type 2 coverage criteria	Susan Glomb	Dr. B. Almasri	August 2012
09	11-29-12	Annual review – no changes.	Susan Glomb	Dr. B. Almasri	Nov. 2012
10	12-30-13	Annual review. Added A9274 External ambulatory insulin delivery system, disposable, each includes al supplies and accessories to the list of "not reasonable and necessary" items.	Susan Glomb	Dr. B. Almasri	Dec. 2013
11	11-24-14	Annual Review. No changes	Susan Glomb	Dr. B. Almasri	
12	12-14-15	Annual Review. Updated Medicare and non-Medicare criteria. Updated references.	Susan Glomb	Dr. B. Almasri	12-14-15