

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 or another non-diabetes based condition causing insulinopenia when members meet the coverage criteria below.

Policy Guidelines

Coverage Criteria:

1. Must be ordered by the member's treating practitioner; and
2. For members that have a diagnosis of diabetes mellitus or another non-diabetes based condition causing insulinopenia, the medical record must show documentation of **ALL** of the following:
 - a. The member has been performing multiple daily injections (MDIs) consisting of at least three injections per day, AND
 - b. The member's current treatment plan involves testing blood glucose at least four times per day ***This requirement does not apply to those members who are currently utilizing Continuous Glucose Monitoring (CGM), AND**
 - c. At least **one** of the following while on a multiple daily injection regimen:
 - i. Glycosylated hemoglobin level (HbA1c) > 7.0 percent; OR
 - ii. History of recurring hypoglycemia; OR
 - iii. The member has experienced fluctuations of more than 100 mg/dL in blood glucose before mealtime; OR
 - iv. Dawn phenomenon with fasting blood sugars frequently exceeding 200 mg/Dl; OR
 - v. History of severe glycemic excursions; AND

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- d. Prior treatments with MDIs were tried and were not effective in managing blood sugars and/or medical symptoms.

Continued Coverage

Continued coverage of an external insulin pump and supplies require that the member be seen and evaluated by the treating practitioner at least every 3 months. There is clinical evidence demonstrating stabilization or improvement of the initial indication for the device. In addition, the external insulin infusion pump must be ordered and follow-up care rendered by a practitioner 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.
3. 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)
 - f. Alcohol, betadine, iodine, PhisoHex solution/swabs/wipes as they are not required for the proper functioning of the insulin infusion system.
 - g. Disposable External Ambulatory Insulin delivery system including all supplies and accessories not reasonable and necessary due to not being standard and basic (this does **not** apply to WellSense MH/MHCP/ACO and WellSense SCO).

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4. Supplies are limited to the **quantities** listed below:

HCPCS Code	Description	Pump Model	Quantity
A4230	Infusion set for external insulin pump; non-needle type	MiniMed	20 per month (2 boxes - 10 per box)
A4231	Infusion set for external insulin pump; needle type	MiniMed	20 per month (2 boxes – 10 per box)
A4232	Supplies for external infusion pump, syringe type cartridge, sterile, each	MiniMed	20 per month (two boxes – 10 per box)
A6257	Transparent dressing	All models	12 per month
A4649	Piston Rod	All models	1 every 12 months
K0601	Replacement battery for external infusion pump owned by patient, silver oxide, 1.5 volt, each	MiniMed	6 per month

HCPCS Level II Codes and Description

A4224	Supplies for maintenance of insulin infusion catheter, per week
A4225	Supplies for external insulin infusion pump, syringe type cartridge, sterile each
A4230	Infusion set for external insulin pump, non-needle cannula type (Not valid for MH/MHCP/ACO and SCO – effective 1/1/24)
A4231	Infusion set for external insulin pump, needle type (Not valid for MH/MHCP/ACO and SCO – effective 1/1/24)
A4232	Syringe with needle for external insulin pump, sterile 3cc (Not valid for MH/MHCP/ACO and SCO – effective 1/1/24)
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
A4649	Surgical supply, miscellaneous (use for batteries, piston rod, adapter)
A5120	MEDICAID ONLY. Skin barrier wipes or swabs, each 50ct. every other

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	month.
A6257	Transparent film, 16 sq. inches or less, each dressing
A6258	Transparent film, sterile, more than 16 sq. in. but less than or equal to 48 sq. in., each dressing. Not reasonable and necessary.
A6259	Transparent film, sterile, more than 48 sq. in., each dressing. Not reasonable and necessary.
A9274	External ambulatory insulin delivery system, disposable, each, includes all supplies and accessories. Not reasonable and necessary due to not being standard and basic (this does not apply to WellSense MH/MHCP/ACO and WellSense SCO).
E0784	External ambulatory infusion pump, insulin
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, 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, alkaline, 3 volt, each
K0605	Replacement battery for external infusion pump owned by patient, lithium, 4.5 volt, each

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

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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 practitioner in connection with diagnosis and treatment decisions.

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

References

MassHealth Guidelines for Medical Necessity Determination for Diabetes Management Devices: Continuous Glucose Monitoring Systems and Insulin Pumps, <https://www.mass.gov/doc/guidelines-for-medical-necessity-determination-for-diabetes-management-devices-continuous-glucose-monitoring-systems-and-insulin-pumps-0/download> Accessed 12/9/24.

Cigna: External Insulin Pumps. http://www.cigna.com/customer_care/healthcare_professional/coverage_positions/medical/mm_0087_coveragepositioncriteria_external_insulin_pumps.pdf Reviewed and accessed December 9, 2024.

Aetna: Infusion Pumps. http://www.aetna.com/cpb/medical/data/100_199/0161.html Last accessed and reviewed 12/9/24.

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>.

CGS Administrators, LLC. Jurisdiction B DME MAC, External Infusion Pumps. Local Coverage Determination No. L33794; Accessed/reviewed December 9, 2024.

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.

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Special Coverage Information Per Plan:

<p>For WellSense MH/MHCP/ACO and SCO only.</p>	<p>1) The OmniPod (A9274) may be approved and is considered medically necessary <i>if</i> the Insulin Infusion Pump policy criteria is met.</p> <p>2) Codes A4230, A4231, A4232 are not valid for these plans – instead use A4224/A4225 effective 1/1/24.</p>
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Change/Authorization History

Revision Number	Date	Description of Change	Prepared by	Approved by	Review Date	Effective Date
A	11-20-06	Initial Release	Rosanne Brugnani	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	

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08	08-29-12	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	05-13-13	Added HCPCS A9274 External ambulatory insulin delivery system, disposable, each, includes all supplies and accessories to the list of “not reasonable and necessary” items. Removed “covered and non-covered” from the HCPCS tables.	Susan Glomb	Dr. B. Almasri	May 2013	
11	12-18-13	Annual review. No changes.	Susan Glomb	Dr. B. Almasri		
12	11-25-14	Annual Review. No changes	Susan Glomb	Dr. B. Almasri		
13	12-14-15	Annual Review. References updated.	Susan Glomb	Dr. B. Almasri	12-14-15	
14	12-28-16	Annual Review. Deleted K0552. Added A 4224 and A4225	Susan Glomb	Dr. B. Almasri		
15	04-17-17	Added to HCPCS A9274 “not reasonable and necessary due to not being standard and basic”.	Susan Glomb	Dr. C. Lerchin		
16	12-20-17	Annual review. No changes.	Carol Dimech	Dr. C. Lerchin	December 2017	
17	12-10-18	Annual review. No changes.	Carol Dimech	Dr. C. Lerchin	December 2018	
18	10-4-19	Added “does not apply to CGM users” to the testing requirement of 4x/day.	Carol Dimech	Dr. C. Lerchin	October 2019	10-4-2019
19	11-4-19	Revised A6257 to allow 12/month. Added codes A6258, A6259 not reasonable and necessary.	Carol Dimech	Dr. C. Lerchin	November 2019	11-4-19

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20	12-12-19	Annual review. Updated Medicare reference.	Carol Dimech	Dr. C. Lerchin	December 2019	December 2019
21	12-3-20	Annual review. Updated policy to reflect OmniPod coverage for Mass Health and Well Sense Plans. Per CMS, revised “physician” to “practitioner”.	Carol Dimech	Dr. C. Lerchin	December 3, 2020	December 3, 2020
22	12-15-21	Annual review. Added NCD/LCD verbiage to Important Note.	Carol Dimech	Dr. C. Lerchin	December 15, 2021	December 15, 2021
23	3-15-22	Updated policy to reflect Plan rebranding by removing “BMCHP” and replacing with “WellSense”	Carol Dimech	Dr. C. Lerchin	3-15-22	3-15-22
24	12-15-22	Annual review. No changes	Carol Dimech, Susan Glomb	Dr. C. Lerchin	12-15-22	
25	7-25-23	Removed reference to Animas supplies as they are no longer in business.	Carol Dimech	Dr. C. Lerchin	7-25-23	7-25-23
26	8-10-23	Updated quantity box to reflect supplies 2 boxes/month (10 per box)	Carol Dimech	Dr. C. Lerchin	8-10-23	8-10-23
27	12-15-23	Annual review. Added references. Revisions to coverage criteria – removed requirement of frequent self-adjustments of insulin dose for at least six months prior to the initiation of the pump, completion of a comprehensive diabetes education program. Added dx of another non-diabetes based condition causing insulinopenia. Added - Prior treatments with MDIs were tried and were not effective in managing blood sugars and/or medical symptoms to the initial qualifying	Carol Dimech	Dr. C. Lerchin	12-15-23	12-15-23

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		criteria. Added - Codes A4230, A4231, A4232 are not valid for MH, MHCP, ACO, SCO – instead use A4224/A4225 effective 1/1/24.				
28	12-9-24	Annual review. References updated.	Carol Dimech	Dr. C. Lerchin	12-9-24	12-9-24