Clinical Policy: Protocols for Authorizing Ambulatory Insulin Pumps

Reference Number: LA.CP.MP.502
Last Review Date: 10/01/2020~~12/20~~ Revision Log

See Important Reminder at the end of this policy for important regulatory and legal information.

Description
To provide guidelines for the authorization of ambulatory insulin pumps. **A continuous subcutaneous insulin external infusion pump is a portable insulin pump. The pump delivers a continuous basal infusion of insulin. Insulin pumps can be automatically programmed for multiple basal rates over a 24 hour time period. This can be useful for such situations as nocturnal hypoglycemia, the dawn phenomenon, and to assist with tight glycemic control.**

Work Process:

1. Purchase of an ambulatory insulin pump is considered medically necessary when ordered by the treating endocrinologist and the applicable state guidelines are met.

2. Medical information which supports the medical necessity determination (received either verbally or hard copy from the requesting endocrinologist office) must be documented in the documentation section of the DME authorization in the clinical documentation system. In addition to a diagnosis, clinical presentation and diabetes management criteria, the requesting and Endocrinologist must also submit information to support Louisiana Medicaid Program Ch. 18 Durable Medical Equipment Section 18.2: specific Coverage Criteria-Continuous Subcutaneous Insulin External Infusion Pumps, pp. 31-33: The Continuous Subcutaneous Insulin External Infusion pump delivers a continuous basal infusion of insulin and can be programmed for multiple basal rates over a 24 hour time period. This can be useful for such situations as nocturnal hypoglycemia, the dawn phenomenon and to assist with tight glycemic control. Payment for a continuous subcutaneous insulin external infusion pump and related supplies will be authorized for treatment of Type I diabetes.

Policy/Criteria

I. It is the policy of Louisiana HealthCare Connections that an ambulatory insulin pump is **medically necessary** for the following indications and must meet criteria from A, B, and C:

A. Member has Type I Diabetes AND meets Criterion in (1 OR 2)
   1. The recipient has completed all of the below **(A,B, C and D):**
      a) **A**~~a~~ comprehensive diabetes education program
      b) **A**~~a~~ program of multiple daily injections of insulin (at least three injections per day) with frequent self-adjustments of insulin dose for at least six months prior to initiation of the insulin pump
      c) **H**~~h~~as documented frequency of glucose self-testing an average of at least four times per day during the two months prior to initiation of the insulin pump

~~d) and meets two or more of the following criteria while on the multiple daily injection regimen:~~

~~e)~~d) Meets two or more of the following criteria while on the multiple daily injection regimen:

i. Has a glycosylated hemoglobin level (HbA1c) greater than 7.0 percent
ii. Has a history of recurring hypoglycemia
iii. Has wide fluctuations in blood glucose levels (regardless of A1C)
iv. Demonstrated microvascular complications
v. Recurrent severe hypoglycemia
vi. Suboptimal diabetes control (A1C exceeds target range for age)
vii. Adolescents with eating disorders
viii. Pregnant adolescents
ix. Ketosis-prone individuals
x. Competitive athletes
xi. Extreme sensitivity to insulin in younger children

OR

2. The ~~recipient~~ **member** with Type I diabetes has been on a pump prior to enrollment in Medicaid and has documented frequency of glucose self-testing an average of at least four times per day during the month prior to Medicaid enrollment.

B. Must present with one of the following:
   1. The ~~recipient~~ **member** with diabetes must be insulinopenic per the updated fasting C-peptide testing requirement OR
   2. ~~m~~**M**ust be autoantibody positive (e.g. islet cell autoantibodies (ICA), glutamic acid decarboxylase (GAD65), the 40K fragment of tyrosine phosphatase (IA2), insulin autoantibodies (IAA) or zinc transporter 8 autoantibodies (ZnT8).

C. Must meet criteria in both 1 & 2 for the following related to updated fasting C-peptide testing requirement:
   1. Insulinopenia (defined as fasting C-peptide level less than or equal to 110 percent of the lower limit of normal of the laboratory's measurement method); and
   2. Fasting C-peptide levels will only be considered valid with a concurrently obtained fasting glucose less than 225mg/dl

Note: Levels only need to be documented once in the medical record. The pump must be ordered by and follow-up care of the ~~recipient~~ **member** must be managed by a physician who has familiarity with continuous subcutaneous insulin infusion (CSII) and who works closely with a team of nurses, diabetes educators and dietitians who are knowledgeable in the use of CSII.

Non-Covered Items DMEPOS

Continuous subcutaneous insulin external infusion pumps shall be denied as not medically necessary for all Type II diabetics, including insulin requiring Type II diabetics. Insulin for

the continuous subcutaneous insulin external infusion pumps must be obtained through the Pharmacy Program and is not covered in the DMEPOS Program.
The Medicaid Program will not cover the replacement of a currently functioning insulin pump for the sole purpose of receiving the most recent insulin pump technology as this would not be medically necessary. The Medicaid Program will not cover additional software or hardware required for downloading data to a device such as a personal computer, smart phone or tablet to aid in self-management of diabetes mellitus.

II. -End date of the initial DME authorization should be no longer than one month from the start date for ambulatory insulin pumps other than OmniPod (see below for OmniPod requirements); Units = 1 (or per Plan specific guidelines).

A. Because the pump is purchased, supplemental equipment such as tubing, filters, etc., needed to operate equipment, are considered incidental and do not require a separate authorization.
B. Some vendors/distributors of the pump may offer educational sessions at the specialist office and/or the patient's home; these vendor supplied services should be included in the price of the pump, and therefore do not require a separate authorization.
C. Visits to the endocrinologist's office do not require a separate authorization unless the provider is not participating with the Plan.
D. Pre-filled insulin cartridges for the pump are a pharmacy benefit and should be obtained from a participating pharmacy. They do not require a separate authorization by the Plan or the pharmacy.
E. Home health care services for nursing visits, etc. will require a separate authorization as described in the clinical documentation system training manual.

III. -Upon initial authorization of an insulin pump, a referral/task is sent to the designated Plan Care Manager for continued management and follow-up.

IV. If replacement device is requested due to loss, damage, etc., documentation to support the need for replacement is required and must be reviewed by the Plan Medical Director for medical necessity. -The Plan Care Manager must verify expiration of original product warranty before authorizing a replacement purchase.

OMNIPOD Insulin Management System

Work Process:

1. The Omni Pod is a disposable external insulin pump with wireless communication capability to a hand –held control unit (PDM) and is an acceptable alternative to a standard insulin infusion pump that is considered medically necessary when the criteria above have been met.
2. End date of the initial DME authorization should be no longer than one year from the start date Units =12. The authorization includes all supplies and accessories.
3. Code A9274 is reimbursable up to 40 insulin delivery devices in a 90-day period. Disposable insulin delivery devices in excess of 40 require submission of documentation of medical necessity.

4. Codes A4230 and A4231 are not separately reimbursable if they are submitted on the same claim or during the same 90-day period.

Reviews, Revisions, and Approvals	Date	Approval Date
Created State of Louisiana specific version of policy	10/2014	
Added OmniPod Insulin Management System work process information; updated definitions, updated references	10/2014	
No revisions	9/2015	
Removed InterQual reference and replaced with LDH manual for insulin pumps as review criteria; Changed "Case" to " Care"	9/2016	
E0784: Insulin pump policy revised as per 12/2016 revision to LA Medicaid policy Continuous Subcutaneous Insulin External Infusion Pumps	6/2018	
Retired Policy: Moving toward InterQual custom criteria set	5/17/2019	
Reinstate Policy: The IQ version has verbiage that is against LDH guidelines so we need a policy to reference until it is placed into IQ	12/20/2019	3/13/2020
Added description of insulin pump per LDH DME provider manual **Changed recipient to member** **Removed duplicate MNC criteria**	**11/2020**	

Definitions:
Insulin Pump (E0784): an external ambulatory infusion device. May also be known as continuous subcutaneous insulin infusion (CSII). OmniPod (A9274): an external ambulatory insulin delivery system, disposable, each, includes all supplies and accessories.

References

1. Louisiana Medicaid Program Ch. 18: DME, Section 18.2: Specific Coverage Criteria: - Continuous Subcutaneous Insulin External Infusion Pumps, pp.31-33. Issued 12/9/16. http://www.lamedicaid.com/provweb1/Providermanuals/manuals/DME/DME.pdf
2. ARQ 5/1/2018: A9274 EXT AMB INSULIN DELIVERY SYS as of 8/15/2016 auto approved.

Important Reminder

This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information. LHCC makes no representations and accepts no

liability with respect to the content of any external information used or relied upon in developing this clinical policy. This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved.

The purpose of this clinical policy is to provide a guide to medical necessity, which is a component of the guidelines used to assist in making coverage decisions and administering benefits. It does not constitute a contract or guarantee regarding payment or results. Coverage decisions and the administration of benefits are subject to all terms, conditions, exclusions and limitations of the coverage documents (e.g., evidence of coverage, certificate of coverage, policy, contract of insurance, etc.), as well as to state and federal requirements and applicable LHCC administrative policies and procedures.

This clinical policy is effective as of the date determined by LHCC. The date of posting may not be the effective date of this clinical policy. This clinical policy may be subject to applicable legal and regulatory requirements relating to provider notification. If there is a discrepancy between the effective date of this clinical policy and any applicable legal or regulatory requirement, the requirements of law and regulation shall govern. LHCC retains the right to change, amend or withdraw this clinical policy, and additional clinical policies may be developed and adopted as needed, at any time.

This clinical policy does not constitute medical advice, medical treatment or medical care. It is not intended to dictate to providers how to practice medicine. Providers are expected to exercise professional medical judgment in providing the most appropriate care, and are solely responsible for the medical advice and treatment of members. This clinical policy is not intended to recommend treatment for members. Members should consult with their treating physician in connection with diagnosis and treatment decisions.

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~~**Note: For Medicaid members**, when state Medicaid coverage provisions conflict with the coverage provisions in this clinical policy, state Medicaid coverage provisions take precedence. Please refer to the state Medicaid manual for any coverage provisions pertaining to this clinical policy.~~

~~**Note: For Medicare members,** to ensure consistency with the Medicare National Coverage Determinations (NCD) and Local Coverage Determinations (LCD), all applicable NCDs, LCDs,~~

~~and Medicare Coverage Articles should be reviewed prior to applying the criteria set forth in this clinical policy. Refer to the CMS website at http://www.cms.gov for additional information.~~