Clinical Policy: Ambulatory Insulin Pumps

Reference Number: LA.CP.MP.502c
Date of Last Revision 4/23

Coding Implications
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. Purchase of an ambulatory insulin pump and related supplies is considered medically necessary for treatment of Type I diabetes and when ordered by the treating provider and the applicable state guidelines are met.

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/enrollee has Type I Diabetes AND meets Criterion in (1 OR 2)

1. The member/enrollee has completed all of the below:
   - a a comprehensive diabetes education program
   - b has been on 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 has 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 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 member/enrollee 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 member/enrollee with diabetes must be insulinopenic per the updated fasting C-peptide testing requirement. Levels only need to be documented once in the medical record.
      a 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)
      b Fasting C-peptide levels will only be considered valid with a concurrently obtained fasting glucose less than 225 mg/dl.
   2. must 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. Batteries are covered for insulin pumps.

The pump must be ordered by and follow-up care of the member/enrollee 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

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 LHCC Pharmacy 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.

Reviews, Revisions, and Approvals	Revision 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	

Reviews, Revisions, and Approvals	Revision Date	Approval Date
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	12/20/19	3/13/20
Under Policy/Criteria section, removed duplicate statement. Changed Date to Revision Date in the revision log. Changed Revision Date to Date of Last Revision. Updated Important Reminder section.	12/2022	2/28/23
Removed section in Work Process 2 regarding the Endocrinologist submitting information to support LA Medicaid Program Ch 18. Added that batteries are covered for insulin pumps Changed recipient to member/enrollee. References reviewed and updated.	4/23	6/1/23

HCPCS:	
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
A4231	Infusion set for external insulin pump, needle type
A9274	External ambulatory insulin delivery system, disposable, each, includes all supplies and accessories
A9999	Miscellaneous DME supply or accessory, not otherwise specified
E0784	External ambulatory infusion pump, insulin
E0787*	External ambulatory infusion pump, insulin, dosage rate adjustment using therapeutic continuous glucose sensing
K0601*	Replacement battery for external infusion pump owned by patient, silver oxide, 1.5 volt, each
E1399	Durable medical equipment, miscellaneous
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, lithium, 3.6 volt, each
K0605*	Replacement battery for external infusion pump owned by patient, lithium, 4.5 volt, each

References

1. Louisiana Medicaid Program Provider Manual Chapter 18: Durable Medical Equipment

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/enrollees. This clinical policy is not intended to recommend treatment for members/enrollees. Members/enrollees should consult with their treating physician in connection with diagnosis and treatment decisions.

Providers referred to in this clinical policy are independent contractors who exercise independent judgment and over whom LHCC has no control or right of control. Providers are not agents or employees of LHCC.