Policy and Procedure

DEPARTMENT: Medical Management	**DOCUMENT NAME:** Protocols for Authorizing Ambulatory Insulin Pumps
PAGE: 1 of 5	**REPLACES DOCUMENT:**
APPROVED DATE: 10/2014	**RETIRED:**
EFFECTIVE DATE:	**REVIEWED/REVISED: 9/15, 9/16. 6/18**
PRODUCT TYPE: Medicaid	**REFERENCE NUMBER:** LA.UM.02.14

SCOPE:
Louisiana Healthcare Connections (Plan) Medical Management and Member Services Departments.

PURPOSE:
To provide guidelines for the authorization of ambulatory insulin pumps.

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.

   Recipients must meet either Criterion A or B as follows:

   Criterion A: The recipient has completed a comprehensive diabetes education program and 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; and 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; and meets two or more of the following criteria while on the multiple daily injection regimen:
   - Has a glycosylated hemoglobin level (HbAlc) greater than 7.0 percent;
   - Has a history of recurring hypoglycemia;
   - Has wide fluctuations in blood glucose levels (regardless of A1C);
   - Demonstrated microvascular complications;

- Recurrent severe hypoglycemia;
- Suboptimal diabetes control (A1C exceeds target range for age);
- Adolescents with eating disorders;
- Pregnant adolescents;
- Ketosis-prone individuals;
- Competitive athletes; and
- Extreme sensitivity to insulin in younger children.

OR

Criterion B: The recipient 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.

3. In addition to meeting Criterion A or B above, the recipient with diabetes must be insulinopenic per the updated fasting C-peptide testing requirement, ***or*** 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).

   Updated fasting C-peptide testing requirement:
   - 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
   - Fasting C-peptide levels will only be considered valid with a concurrently obtained fasting glucose less than 225 mg/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 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.

4. End date of the initial DME authorization should be **no longer than one (1) 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.

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

6. 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 OmniPod 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 (1) year** from the start date **Units = 12.** The authorization includes all supplies and accessories.
3. Code **A9274** is reimbursable up to 40 disposable 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.

REFERENCES:

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
3. ARQ 5/1/2018: A9274 EXT AMB INSULIN DELIVERY SYS as of 8/15/2016 auto approved

ATTACHMENTS:

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.

REVISION	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	9/15
Removed InterQual reference and replaced with LDH manual for insulin pumps as review criteria; Changed “Case” to “Care”	9/16

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E0784: Insulin pump policy revised as per 12/2016 revision to LA Medicaid policy Continuous Subcutaneous Insulin External Infusion Pumps	6/2018

AUTHORIZATION PROTOCOLS APPROVAL

The electronic approval retained in Compliance 360, Centene's P&P management software, is considered equivalent to a physical signature.

Vice-President of Medical Management: Signature on File
Chief Medical Director: Signature on File