POLICY AND PROCEDURE

POLICY NAME: Review of External Insulin Pumps	**POLICY ID:** FL.UM.19
BUSINESS UNIT: Sunshine State Health Plan	**FUNCTIONAL AREA:** Utilization Management
EFFECTIVE DATE: 06/2015	**PRODUCT(S):** Managed Medical Assistance (MMA), Child Welfare (CW), and Long Term Care (LTC), Children's Medical Services (CMS)
REVIEWED/REVISED DATE: 06/02/15, 9/4/15, 9/15/16, 11/17, 3/2018, 04/2019, 05/2020, 7/2021, 07/2022, 07/2023	
REGULATOR MOST RECENT APPROVAL DATE(S): 06/10/2015	

POLICY STATEMENT: It is the policy of Sunshine Health to cover external insulin pumps when medically necessary and covered under the member's specific benefit plan. Sunshine Health considers coverage of external insulin pumps when appropriate and consistent with good medical practice, and after review on an individual basis, for the specific indications outlined in this policy.

PURPOSE: To establish clinical criteria on which to review requests for external insulin pumps for Sunshine Health's MMA, CW, CMS and LTC lines of business. The goal is to provide external insulin pumps when medically necessary and to define criteria and limitations established for the use of External insulin pumps in members with Type I and Type II diabetes.

SCOPE: Sunshine Health Utilization Department for Managed Medical Assistance (MMA), Child Welfare (CW), Children's Medical Services (CMS) and Long Term Care (LTC) product lines.
This policy applies to all directors, officers, and employees of Centene Corporation, its affiliates, health plans, and subsidiary companies (collectively, the "Company").

DEFINITIONS:
External Insulin Pumps are devices used as an alternative to multiple daily injections of insulin and allows for intensive therapy of subcutaneous insulin for the treatment of diabetes mellitus Type I and II. Acting in conjunction with blood glucose monitoring, carbohydrate counting, and dieting, external insulin pumps deliver both short-acting and rapid insulin over a 24-hour period. External pumps are a vital part of a physician's goal of lowering A1C levels and achieving control over blood sugar levels.

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PROCEDURE:
Review Process
To assist in determining the medical necessity of an external insulin pump or associated supplies, the clinical criteria established in this policy will be applied. A request for medical necessity review is consistent with Sunshine Health medical policies:

- FL.UM.02.01 - Medical Necessity Review and Continuity of Care
- FL.UM.02.00 – Use of Clinical Criteria
- Any decision to deny, reduce, suspend or terminate services must be made by a Sunshine Health Medical Director as outlined in the policy Use of Clinical Criteria FL.UM.02.00
- Determinations and provider notifications will be made according to the expediency of the case as described in the Timeliness of UM Decisions and Notifications FL.UM.05.00

Specific Clinical Information/Criteria
The requesting physician must provide information on the specific type of external insulin pump that is being requested.

An external insulin pump is considered medically necessary when all of the following criteria are met:

- The requesting physician manages multiple patients on subcutaneous insulin therapy, and works closely with a team of nurses, diabetic educators, and dietitians who are knowledgeable and trained in the use of continuous subcutaneous insulin infusion therapy.
- The member has been receiving documented treatments of at least three insulin injections per day and self-adjusts with frequent self-administration of insulin for at least six months prior to the request for the initiation of the external pump; and the member has documented blood glucose self-testing on an average of at least four times per day, from testing for two months prior to the request for the initiation of the external pump.

- The member has documentation of having completed a diabetes self-management educational program, is motivated, and demonstrates knowledge in the use of the device
- The member meets at least one of the following criteria, while on the multiple daily injection program:
    - History of severe glycemic excursions (including history of reoccurring hypoglycemia)
    - Glycosylated hemoglobin level (HbA1C) of more than 7.0%
    - Wide fluctuations in blood glucose before or after meals
    - A physiological increase in blood sugar levels >180 mg/dl, especially in the early morning before breakfast due to insufficient insulin being produced overnight despite fasting.
    - Dawn phenomenon with BG > 200 mg/dL
    - Recurrent DKA

The requested insulin pump must have FDA approval.

Information Required for Review
The following information and documentation should be submitted with any request for an external insulin pump and supplies, in order to assess medical necessity:

- Medical documentation as noted above in the "**Specific Clinical Information/Criteria"** section
- The type of equipment requested

Redetermination
Prior to the expiration of the initial authorization period, the requesting provider must submit to Sunshine Health's utilization management department information on the member's status in order for a review for subsequent approvals using the "Specific Clinical Information/Criteria" stated in this policy.

Limitations / Exclusions
The following limitations or exclusions apply:

- Implantable insulin pumps are not covered.
- Chronic Intermittent Intravenous Insulin Therapy (CIIIT) is considered experimental and investigational.
- External insulin pumps which are not approved by the FDA will not be covered.

REFERENCES:

Agency for Health Care Administration (AHCA) Florida Medicaid Durable Medical Equipment and Medical Supply Services Provider Fee Schedule for All Medicaid Recipients
AHCA Florida Durable Medical Equipment and Coverage Handbook. Updated July 2010
FL.UM.05.00 Timeliness of UM Decisions and Notifications policy and procedure
FL.UM.02.00 Use of Clinical Criteria
FL.UM.02.01 Medical Necessity Review and Continuity of care
*Web*MD. Diabetes Health Center. Diabetes and Morning High Blood Sugar. Source: American Diabetes Association. Reviewed: June 15, 2012. http://diabetes.webmd.com/morning-high-blood-sugar-levels
Danne T, Lange K, Kodonouri O: New developments in the treatment of Type I diabetes in children. Arch Dis Child. 2007 Nov; 92(11):0:1015-1019. http://www.ncbi.nlm.nih.gov/pmc/articles/PMC2083598/pdf/1015.pdf

ATTACHMENTS: N/A

ROLES & RESPONSIBILITIES: Utilization Management

REGULATORY REPORTING REQUIREMENTS: N/A

REVISION LOG

REVISION TYPE	REVISION SUMMARY	DATE APPROVED & PUBLISHED
New Policy Document	Policy Created	06/02/2015
Policy Update	Added: Healthy Kids	09/04/2015
Annual Review	No changes needed	09/15/2016
Annual Review	Updated references; Updated clinical indications for an external insulin pump to include: Dawn phenomenon with BG > 200 mg/dL o Recurrent DKA	11/02/2017

	• If a CGM (Continuous Glucose Monitor) is requested, ALL of the following is required: ○ Age >8 years old ▪ The member is willing to do supplemental blood sugar monitoring for accuracy, in conjunction with the CGM. ▪ Has the cognitive ability to respond to alarms ▪ Has no significant Behavioral Health conditions that need treatment ▪ Drug or alcohol misuse are excluded ○ Age 4-8 years old ▪ DM Type I only ▪ Documented compliance to physician-directed diabetes management program ▪ Caregiver is motivated ▪ Frequent hypoglycemic events ▪ Blood sugar is checked regularly ○ Age < 4 : Not recommended.	
Annual Review	No changes needed	03/2018
Annual Review	• Added "and continuity of care" to policy title and changed reference number from FL.UM.19 to FL.UM.19.00 • Deleted reference to FL.UM.02.02 Clinical Decision Criteria and Application"	04/2019

	Updated Review Process section policy numbers reference and added “and Continuity of Care” and “Notifications FL.UM.05.00”	
Annual Review	Deleted reference to HK, changed approver #3 to VP, Medical Affairs	05/2020
Annual Review	No changes needed	07/20221
Annual Review	Add CMS to LOB	07/25/2022
Annual Review	Update Policy ID Added Policy ID and Name to “Footer” Remove CGM Guidelines	07/2023

POLICY AND PROCEDURE APPROVAL

The electronic approval retained in RSA Archer, the Company’s P&P management software, is considered equivalent to a signature.