POLICY AND PROCEDURE

POLICY NAME: Ambulatory Infusion Pump Expanded Benefit	**POLICY ID:** FL.UM.22
BUSINESS UNIT: Sunshine State Health Plan	**FUNCTIONAL AREA:** Utilization Management
EFFECTIVE DATE: 11/2018	**PRODUCT(S):** Managed Medical Assistance (MMA), including Comprehensive members (MMA and Long Term Care with Sunshine Health)
REVIEWED/REVISED DATE: 07/2018, 05/2019, 06/2020, 07/2021, 07/2022, 07/2023	
REGULATOR MOST RECENT APPROVAL DATE(S): N/A	

POLICY STATEMENT: It is the policy of Sunshine Health to cover Agency for Health Care Administration (AHCA) approved expanded benefit when medically necessary, 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 an Ambulatory Infusion Pump as an expanded benefit for Sunshine Health's Managed Medical Assistance (MMA) product including those who are Comprehensive members (MMA and Long Term Care with Sunshine Health). The goal is to provide ambulatory infusion pumps when medically necessary, as an expanded benefit and to define criteria and limitations established for the use ambulatory infusion pumps.

SCOPE: Sunshine Health Utilization Department for Managed Medical Assistance (MMA) product including those who are Comprehensive members (MMA and Long Term Care with Sunshine Health).
This policy applies to all directors, officers, and employees of Centene Corporation, its affiliates, health plans, and subsidiary companies (collectively, the "Company").

DEFINITIONS:
Infusion pumps may be capable of delivering fluids in large or small amounts and may be used to deliver nutrients or medications – such as insulin or other hormones, antibiotics, chemotherapy drugs, and pain relievers.

Some infusion pumps are designed mainly for stationary use at a patient's bedside. Others, called ambulatory infusion pumps, are designed to be portable or wearable.

POLICY:
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PROCEDURE:
Review Process: To assist in determining the medical necessity of an expanded benefit, 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 Clinical Decision Criteria and Application 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
Initial review:
Ambulatory infusion pumps are considered medically necessary when a written order is received, and the following criteria are met:

- A detailed written order is received
- Administration of deferoxamine for the treatment of chronic iron overload
- Administration of chemotherapy for the treatment of primary hepatocellular carcinoma or colorectal cancer where this disease is unresectable or where the beneficiary refuses surgical excision of the tumor.
- Administration of morphine when used in the treatment of intractable pain caused by cancer.
- Administration of continuous subcutaneous insulin for the treatment of diabetes mellitus if criterion A or B is met and if criterion C or D is met:
    A. C-peptide testing requirement – must meet criterion 1 or 2 and criterion 3:

1. C-peptide level is less than or equal to 110 percent of the lower limit of normal of the laboratory's measurement method.
2. For members with renal insufficiency and a creatinine clearance (actual or calculated from age, weight, and serum creatinine) less than or equal to 50 ml/minute, a fasting C-peptide level is less than or equal to 200 per cent of the lower limit of normal of the laboratory's measurement method.
3. A fasting blood sugar obtained at the same time as the C-peptide level is less than or equal to 225 mg/dl.

B. Beta cell autoantibody test is positive.

C. The member has completed a comprehensive diabetes education program, has been on a program of multiple daily injections of insulin (i.e., at least 3 injections per day) with frequent self-adjustments of insulin dose for at least 6 months prior to initiation of the insulin pump, and has documented frequency of glucose self-testing an average of at least 4 times per day during the 2 months prior to initiation of the insulin pump, and meets one or more of the following criteria (1 - 5) while on the multiple injection regimen:
   1. Glycosylated hemoglobin level (HbA1C) greater than 7 percent
   2. History of recurring hypoglycemia
   3. Wide fluctuations in blood glucose before mealtime
   4. Dawn phenomenon with fasting blood sugars frequently exceeding 200 mg/dL
   5. History of severe glycemic excursions

D. The member has been on an external insulin infusion pump prior to enrollment and has documented frequency of glucose self-testing an average of at least 4 times per day during the month prior to enrollment with Sunshine Health.

Re-Determination:
Continued coverage of an ambulatory infusion pump and supplies requires that the member be seen and evaluated by the treating physician at least every 3 months and the above criteria must also be met.

Limitations / Exclusions
The following limitations or exclusions apply:

- An ambulatory infusion pump and related drugs and supplies are excluded as they are not reasonable and necessary in the home setting for the treatment of thromboembolic disease and/or pulmonary embolism by heparin infusion.

REFERENCES:
Center for Devices and Radiological Health. (n.d.). Infusion Pumps - What Is an Infusion Pump? Retrieved from https://www.fda.gov/medicaldevices/productsandmedicalprocedures/generalhospitaldevicesandsupplies/infusionpumps/ucm202495.htm

License Agreements. (n.d.). Retrieved from https://www.cms.gov/medicare-coverage-database/details/lcd-details.aspx?LCDId=33794&ver=77&Date=&DocID=L33794&bc=iAAAABAAAAAA&

National Coverage Determination (NCD) for Infusion Pumps (280.14). (n.d.). Retrieved from https://www.cms.gov/medicare-coverage-database/details/ncd-details.aspx?NCAId=109&NCDId=223&ncdver=2&ver=17&NcaName=Insulin Pump*3a$ C-Peptide Levels as a Criterion for Use (1st Recon)&fromdb=true&bc=BEAAAAAACAAA&

FL.UM.05.00_Timeliness of UM Decisions and Notifications
FL.UM.02_Use of Clinical Criteria
FL.UM.02.01_Medical Necessity Review and Continuity of Care

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	07/2018
Annual Review	Archer reload to fix system issue - No content reviewed or revised	05/2019
Annual Review	updated policy names and numbers and changed approver 3 to VP Medical Affairs	06/2020
Annual Review	No changes needed	07/2021
Annual Review	No changes needed	07/2022
Annual Review	Updated “Policy ID” Updated dates to the correct format Added policy name to “Footer” Removed Signature Lines Corrected grammatical errors	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.