Clinical Policy: Omnipod Insulin Pump

Reference Number: OH.PHAR.PPA.19
Effective Date: 02.01.19
Last Review Date: 02.19
Line of Business: Medicaid

Revision Log

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

Description

Omnipod® Insulin Pump is a tubeless insulin pump that consists of a small Pod and a handheld Personal Diabetes Manager that communicate wirelessly to deliver continuous insulin.

Policy/Criteria

Provider must submit documentation (including such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.
Initial Limits: 1 Personal Diabetes Manager device every 4 years; 10 pods per 30 days (additional documentation required to support medical necessity for more pods per month)

It is the policy of Buckeye Health Plan that Omnipod® Insulin Pump is **medically necessary** when the following criteria are met:

I. Initial Approval Criteria

A. Type 1 Diabetes Mellitus (must meet all)**:**

1. Diagnosis of Type 1 Diabetes Mellitus;
2. Member has completed a diabetes education program within the preceding 24 months.
3. Member has been on a maintenance program for at least 6 months involving at least THREE injections of insulin per day and frequent self-adjustments of insulin dosage.
4. Member (or someone assisting member) has performed glucose self-testing at least FOUR times per day on average during the preceding month.
5. the ability to perform glucose self-testing at least FOUR times per day.
6. Member is at high risk for preventable complications of diabetes.
7. Member (or someone assisting member) is capable of managing the pump and that the desired improvement in metabolic control can be achieved.
8. Member has one or more of the following symptoms or conditions (note all that apply):
    a. HbA1c greater than 7%
    b. History of recurring hypoglycemia
    c. Wide fluctuations in blood glucose before mealtime
    d. A marked early morning increase in fasting blood sugar (Dawn Phenomenon – glucose level exceeds 200mg/dl)
    e. History of severe glycemic excursions

9. If request is for more than 10 pods per 30 days additional documentation is required to provide clinical rationale for higher quantity.

Approval duration: 12 months

B. Other diagnoses/indications

1. Refer to CP.PMN.53 if diagnosis is NOT Type 1 Diabetes Mellitus.

II. Continued Therapy

A. Type 1 Diabetes Mellitus (must meet all)**:**

1. Currently receiving medication via Buckeye benefit or member has previously met initial approval criteria;
2. Member (or someone assisting the member) is capable of managing the pump and that the desired improvement in metabolic control can be achieved;
3. There is documented evidence of improvement in control of diabetes (specific to baseline status of disease for individual members).

Approval duration: 12 months

B. Other diagnoses/indications (must meet 1 or 2)**:**

1. Currently receiving medication via Buckeye benefit and documentation supports positive response to therapy.
   Approval duration: Duration of request or 12 months (whichever is less); or
2. Refer to CP.PMN.53 if diagnosis is NOT Type 1 Diabetes Mellitus.

III. Product Availability

- Omnipod Starter Kit
- Omnipod 5 Pack
- Omnipod Dash System
- Omnipod Dash 5 Pack

IV. Revision Log

Reviews, Revisions, and Approvals	Date	P&T Approval Date
Policy created.	01.19	

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. The Health Plan 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. "Health Plan" means a health plan that has adopted this clinical policy and that is operated or administered, in whole or in part, by Centene Management Company, LLC, or any of such health plan's affiliates, as applicable.

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 Health Plan-level administrative policies and procedures.

This clinical policy is effective as of the date determined by the Health Plan. 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. The Health Plan 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.

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

This clinical policy is the property of the Health Plan. Unauthorized copying, use, and distribution of this clinical policy or any information contained herein are strictly prohibited. Providers, members and their representatives are bound to the terms and conditions expressed herein through the terms of their contracts. Where no such contract exists, providers, members and their representatives agree to be bound by such terms and conditions by providing services to members and/or submitting claims for payment for such services.

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.