MEDICAL POLICY STATEMENT
Indiana Medicaid

Policy Name & Number	Date Effective
Insulin Infusion Pump-IN MCD-MM-0701	09/01/2022-12/31/2022
Policy Type	
MEDICAL	

Medical Policy Statement prepared by CareSource and its affiliates are derived from literature based on and supported by clinical guidelines, nationally recognized utilization and technology assessment guidelines, other medical management industry standards, and published MCO clinical policy guidelines. Medically necessary services include, but are not limited to, those health care services or supplies that are proper and necessary for the diagnosis or treatment of disease, illness, or injury and without which the patient can be expected to suffer prolonged, increased or new morbidity, impairment of function, dysfunction of a body organ or part, or significant pain and discomfort. These services meet the standards of good medical practice in the local area, are the lowest cost alternative, and are not provided mainly for the convenience of the member or provider. Medically necessary services also include those services defined in any Evidence of Coverage documents, Medical Policy Statements, Provider Manuals, Member Handbooks, and/or other policies and procedures.

Medical Policy Statements prepared by CareSource and its affiliates do not ensure an authorization or payment of services. Please refer to the plan contract (often referred to as the Evidence of Coverage) for the service(s) referenced in the Medical Policy Statement. If there is a conflict between the Medical Policy Statement and the plan contract (i.e., Evidence of Coverage), then the plan contract (i.e., Evidence of Coverage) will be the controlling document used to make the determination. According to the rules of Mental Health Parity Addiction Equity Act (MHPAEA), coverage for the diagnosis and treatment of a behavioral health disorder will not be subject to any limitations that are less favorable than the limitations that apply to medical conditions as covered under this policy.

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A. Subject
Insulin Infusion Pump

B. Background
37.3 million people (11.3% of the population) in the United States have diabetes (DM), not including the estimated 8.5 million adults who are undiagnosed. Approximately 5 to 10% of individuals with diabetes have Type 1, while Type 2 accounts for the remaining 90 to 95% of cases. The incidence of both Type 1 and Type 2 in children and adolescents has significantly increased, according to the Centers for Disease Control (CDC) National Diabetes Statistic Report. Some of the unique challenges associated with caring for children and adolescents include the patient's size, developmental concerns, and inability to communicate symptoms of hypoglycemia. Health care resources spent on diabetes are considered to be higher than all other health conditions. Immediate impacts on both physical and mental well-being are common with both severe hypoglycemia and extreme hyperglycemia.

Patients with diabetes need to be closely monitored. When blood glucose levels are poorly controlled, patients are at risk of complications, including heart disease, stroke, peripheral vascular disease, retinal damage, kidney disease, nerve damage, and impotence. Patients should also be monitored for comorbidities that may not be present during the early stages of the disease, but develop as the disease progresses, including hearing impairment, fatty liver disease, sleep apnea, periodontal disease, depression, anxiety, cognitive impairment, and fractures.

Reasonable glycated hemoglobin (A1C) goals for diabetic patients should be customized for the individual patient balancing established benefits with prevention of complications and risk of hypoglycemia. Goals vary depending on age, comorbidities, and the benefits of intensive therapy. Patients with Type 1 diabetes while pregnant may require stricter control.

Insulin therapy is the mainstay of treatment for type 1 diabetes mellitus and insulin dependent type 2 diabetes. External insulin pumps are an option for intensive insulin therapy designed to provide continuous subcutaneous insulin infusion (CSII) to improve glycemic control, meet basal insulin requirements and supplement bolus insulin delivery to assist in mealtime insulin needs. The American Association of Clinical Endocrinologists (AACE), American College of Endocrinology (ACE), and American Diabetes Association (ADA) recommend CSII only in individuals with T1D and patient with T2D who are insulin dependent. Insulin absorption with CSII therapy appears to be less variable and may help members that have not been able to achieve optimum glycemic goals on multiple daily injections. The choice of insulin delivery via multiple daily injections or continuous subcutaneous delivery of a rapid-acting insulin preparation via a pump should be carefully considered and thoroughly explained to the member. Insulin pumps should only be used in patients who are motivated and knowledgeable in DM self-care and able to safely manage the device. Additionally, newer, sensor-augmented insulin pump systems are available with continuous glucose monitoring integrated into the pump, which may reduce nocturnal hypoglycemia.

C. Definitions

- **Dawn Phenomenon -** An observed increase in blood sugar levels that takes place in the early morning, often between 2am and 8am.
- **Insulin Infusion Pump -** An external pump used to deliver insulin subcutaneously or through an intraperitoneal route in a controlled and programmed way in order to prevent acute metabolic complications of the disease and obtain normal blood glucose levels.
- **Moderately Increased Albuminuria -** Persistent urine albumin-to-creatinine ratio values between 30 and 300mg/gram creatinine. Previously called microalbuminuria, this is usually indicative of diabetic nephropathy (unless there is some other coexistent renal disease).
- **Sensor-Augmented Insulin Pump System -** An insulin infusion pump equipped with a continuous glucose monitoring (CGM) sensor. The pump uses the glucose readings taken by the CGM sensor to modify the amount of insulin infused.

D. Policy

I. A prior authorization is required for the use of external insulin infusion pumps and ancillary supplies.

II. Insulin infusion pumps and their ancillary supplies are considered medically necessary when **ALL** the following criteria are met:

A. Documented diagnosis of one of the following:
   1. Type 1 diabetes;
   2. Type 2 diabetes WITH insulin dependency;
   3. Member is pregnant and has type 1, type 2, or gestational diabetes;

B. The member's provider and provider team has an expert level of experience in the management and support of members with insulin infusion pumps;

C. The member has completed a diabetes education program within the last 24 months and is available upon request;

D. The member or member's caregiver must be knowledgeable in operating the device;

E. The member has been on a maintenance program for at least 6 months involving at least 3 injections of insulin per day requiring frequent self-adjustments of insulin dosage;

F. The member has performed glucose self-testing at least 4 times per day on average during the last month;

G. The member is at high risk for preventable complications of diabetes, early signs of which include:
   1. Moderately increased albuminuria (e.g., microalbuminuria);
   2. Persistent difficulty in controlling blood sugar levels despite good compliance with an intensive multiple-injection regimen, as indicated in documented member log; and
   3. Evidence of insulin-induced hypoglycemia (<50 mg/dL) occurring multiple times per week;

H. The member has **at least ONE** of the following symptoms or conditions:

1. Glycated hemoglobin level (A1c) is greater than 7%;
2. A history of recurring hypoglycemia unawareness resulting in loss of consciousness, seizure, or need for emergency health services;
3. Wide fluctuations in blood glucose before mealtime;
4. Dawn phenomenon frequently exceeding 200 mg/dl;
5. A history of severe glycemic excursions.

III. Exclusions

A. CareSource considers insulin therapy not medically necessary when any of the following apply:
   1. Member has end-stage complications such as renal failure.
   2. Neither the member or anyone assisting the member is able to operate a pump or to perform frequent blood glucose monitoring.

B. CareSource considers the following devices not medically necessary:
   1. Portable external insulin infusion pumps that are requested for purely convenience or member preference.
   2. Surgically implanted infusion devices for systems.
   3. Jet pressure devices.
   4. Devices associated with chronic intermittent intravenous insulin therapy (CIIIT).
   5. Devices associated with pulsatile intravenous therapy (PIVIT).

E. Conditions of Coverage

NA

F. Related Policies/Rules

NA

G. Review/Revision History

	DATE	ACTION
Date Issued	05/13/2020	New Policy
Date Revised	04/28/2021 03/29/2022	Annual Update: Added additional clinical criteria, including: coverage of gestational diabetes; evidence of hypoglycemia and hypoglycemia unawareness requirement. Annual Review: updated references and background, added Dawn Phenomenon and moderately increased albuminuria to definitions.
Date Effective	09/01/2022	
Date Archived	12/31/2022	This Policy is no longer active and has been archived. Please note that there could be other Policies that may have some of the same rules incorporated and CareSource reserves the right to follow CMS/State/NCCI guidelines without a formal documented Policy.

H. References

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