



Qualified Health Plans offered in North Carolina by CareSource North Carolina Co., d/b/a CareSource

MEDICAL POLICY STATEMENT	
North Carolina Marketplace	
Policy Name & Number	Date Effective
Insulin Infusion Pump-NC MP-MM-1371	06/01/2024
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**

38.4 million people (11.6% of the population) in the United States have diabetes mellitus (DM), not including the estimated 8.5 million adults who are undiagnosed. Approximately 5 to 10% of individuals with diabetes have type 1 (T1D), while type 2 (T2D) accounts for the remaining 90 to 95% of cases. The incidence of both T1D and T2D 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 T1D while pregnant may require stricter control.

Insulin therapy is the mainstay of treatment for T1D and insulin dependent T2D. 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 patients with T2D who are insulin dependent. Insulin absorption with CSII therapy appears to be less variable and may help members unable to achieve optimum glycemic goals with 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 (CGM) integrated into the pump, which may reduce nocturnal hypoglycemia.

The MEDICAL Policy Statement detailed above has received due consideration as defined in the MEDICAL Policy Statement Policy and is approved.

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 diabetes 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 CGM sensor that uses the glucose readings taken by the CGM sensor to modify the amount of insulin infused.

D. Policy

- I. CareSource considers the use of external insulin infusion pumps medically necessary when **ALL** the following criteria are met:
 - A. Documented diagnosis of one of the following:
 1. T1D
 2. T2D with insulin dependency
 - B. Diabetic education, equipment, and supplies must be ordered in writing by a physician or a podiatrist.
 - C. The member's provider and provider team have an expert level of experience in the management and support of members with insulin infusion pumps.
 - D. Documentation that the patient has completed a comprehensive diabetes education program within the last 12 months by a certified, registered, or licensed provider with expertise in diabetes.
 - E. The member or member's caregiver must be knowledgeable in operating the device.
 - F. 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.
 - G. The member has performed glucose self-testing at least 4 times per day on average during the last month.
 - H. The member is at high risk for preventable complications of diabetes, early signs of which include:
 - a. moderately increased albuminuria (eg, microalbuminuria)
 - b. persistent difficulty in controlling blood sugar levels despite compliance with an intensive multiple-injection regimen, as indicated in documented member log
 - I. The member has at least one of the following symptoms or conditions:
 - a. A1C greater than 7%
 - b. history of recurring hypoglycemia
 - c. wide fluctuations in blood glucose before mealtime
 - d. dawn phenomenon frequently exceeding 200 mg/dl

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- e. history of severe glycemc excursions

II. Exclusions

- A. CareSource considers insulin pump therapy not medically necessary when any of the following apply:
 - 1. Member has end-stage complications such as renal failure.
 - 2. Neither the member, nor 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 purely for convenience or member preference
 - 2. surgically implanted infusion devices for systems
 - 3. jet pressure devices
 - 4. devices associated with chronic intermittent intravenous insulin therapy (CIIT)
 - 5. devices associated with pulsatile intravenous therapy (PIVIT)

III. Device Replacement or Repair

CareSource may cover the repair, adjustment, and/or replacement of purchased equipment, supplies, or appliances when approved.

- A. The repair, adjustment, or replacement of the purchased equipment, supply, or appliance is covered if:
 - 1. The equipment, supply, or appliance is a covered service.
 - 2. The continued use of the item is medically necessary.
 - 3. There is reasonable justification for the repair, adjustment, or replacement.
- B. Replacement of a functioning device just because the warranty has expired is not considered medically necessary.
- C. Replacement of purchased equipment, supplies or appliances may be covered if:
 - 1. The equipment, supply or appliance is worn out or no longer functions.
 - 2. Repair is not possible or would equal or exceed the cost of replacement. An assessment by a rehabilitation equipment specialist or vendor should be done to estimate the cost of repair.
 - 3. The member's needs have changed, and the current equipment is no longer usable due to weight gain, rapid growth, or deterioration of function, etc.
 - 4. The equipment, supply or appliance is damaged and cannot be repaired.
 - 5. Benefits for repairs and replacement do not include:
 - a. repair and replacement due to misuse, malicious breakage, or gross neglect
 - b. replacement of lost or stolen items

E. Conditions of Coverage

N/A

F. Related Policies/Rules

N/A

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G. Review/Revision History

DATE		ACTION
Date Issued	04/13/2022	
Date Revised	03/29/2023	Annual review: updated references. Approved at Committee.
	03/13/2024	Annual review: editorial changes, updated background, and updated references. Approved at Committee.
Date Effective	06/01/2024	
Date Archived		

H. References

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Independent medical review – April 2020

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