MEDICAL POLICY STATEMENT
INDIANA MEDICAID

Policy Name		Policy Number	Date Effective
Insulin Infusion Pump		MM-0701	10/01/2020
Policy Type			
MEDICAL	Administrative	Pharmacy	Reimbursement

Medical Policy Statement prepared by CSMG Co. and its affiliates (including CareSource) 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 CSMG Co. and its affiliates (including CareSource) 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.

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A. Subject

Insulin Infusion Pump

B. Background

34.2 million people or 10.5 percent of the population in the United States have diabetes (DM). This does not include the estimated 7.3.million adults aged 18 years or older that are considered undiagnosed. 5 to 10% of cases in the United States, Canada and Europe include Type 1, Type 2 accounts for the remaining 90% 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's (CDC's) National Diabetes Statistic Report. Some of the unique challenges associated with caring for children and adolescents include size of the patient and inability to communicate symptoms of hypoglycemia. Health care resources spent on diabetes are considered to be the highest among all other health conditions. Immediate impacts on both physical and mental well-being are common with 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, impotence and nerve damage. 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, these include: 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, patients with comorbidities, limited lifetime expectancy and benefits of intensive therapy. Patients with Type 1 Diabetes and pregnancy may require stricter control.

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. 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. Additionally newer sensor-augmented insulin pump systems are available with continuous glucose monitoring integrated into the pump, which may reduce nocturnal hypoglycemia.

Professional Society Recommendations:

The following professional society's recommendations are derived from the latest guidelines and scientific based literature available.

American Association of Clinical Endocrinologists (AACE)/ American College of Endocrinology (ACE) (2015)

- Candidates for CSII Candidates for CSII include patients with T1D and patients with T2D who are insulin dependent
- CSII should only be used in patients who are motivated and knowledgeable in DM self-care, including insulin adjustment.
- To ensure patient safety, prescribing physicians must have expertise in CSII therapy, and CSII users must be thoroughly educated and periodically reevaluated.
- Sensor-augmented CSII, including those with a threshold-suspend function, should be considered for patients who are at risk of hypoglycemia

C. Definitions

- **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.
- **Sensor-Augmented Insulin Pump System -** Is 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 is considered medically necessary when the following clinical criteria are met:
   A. Documented diagnosis of Type 1 or Type 2 Diabetes (if Type 2, must be insulin dependent) and meet All of the following:
      1. The member's provider and provider team has an expert level of experience in the management and support of members with insulin infusion pumps.
      2. The member has completed a diabetes education program within the last twenty-four (24) months and is available upon request.
         a. The member or member's caregiver must be knowledgeable in operating the device.
      3. The member has been on a maintenance program for at least six (6) months involving at least three (3) injections of insulin per day and frequent self-adjustments of insulin dosage;
      4. The member has performed glucose self-testing at least four (4) times per day on average during the last month;
      5. The member is at high risk for preventable complications of diabetes, early signs of which include:
         a. Micro-albuminuria; and

b. Persistent difficulty in controlling blood sugar levels despite good compliance with an intensive multiple-injection regimen, as indicated in documented member log.

AND

6. The member has at least ONE of the following symptoms or conditions:
   a. Glycated hemoglobin level (A1c) is greater than 7%;
   b. A history of recurring hypoglycemia;
   c. Wide fluctuations in blood glucose before mealtime;
   d. Dawn phenomenon frequently exceeding 200 mg/dl; or
   e. A history of severe glycemic excursions

II. Exclusions
   A. Member has end-stage complications such as renal failure;
   B. Neither the member or anyone assisting the member is able to operate a pump or to perform frequent blood glucose monitoring;
   C. Portable external insulin infusion pumps that are requested for purely convenience or member preference;
   D. Surgically implanted infusion devices for systems;
   E. Jet pressure devices;
   F. Devices associated with chronic intermittent intravenous insulin therapy (CIIIT); or
   G. Devices associated with pulsatile intravenous therapy (PIVIT).

E. Conditions of Coverage

F. Related Policies/Rules

G. Review/Revision History

	DATE	ACTION
Date Issued	05/13/2020	New Policy
Date Revised		
Date Effective	10/01/2020	
Date Archived	TBD	

H. References

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

Independent medical review – April 2020

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