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Developed By: Medical Criteria Committee	

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Description:

An insulin pump is an external battery operated device that delivers subcutaneous insulin into the body in a programmed and controlled manner. It is indicated for insulin-dependent diabetics whose blood glucose levels cannot be controlled by intermittent insulin dosing even with maximal patient compliance. The goal of an insulin pump is to achieve near-normal blood glucose levels, to prevent acute metabolic complications and to delay the onset and progression of late-stage secondary macrovascular and microvascular complications of diabetes.

Criteria:

ODS will cover external insulin pumps to plan limitations when **ONE** of the four following criteria is met:

1. All the following criteria must be met for adults or children:
 - a. Three or more insulin doses are required per day using mixed long-acting/short acting insulin for a period of 6 months; **and**
 - b. Erratic blood sugar, ketoacidosis or symptomatic hypoglycemia despite maximal patient compliance with intermittent dosing; **and**
 - c. The patient has documentation of glucose self-testing an average of 4 times per day during the 2 months prior to initiation of the insulin pump; **and**
 - d. The patient has completed a diabetes self-management education program; **and**
 - e. The patient meets at least **one** of the following criteria while on the multiple daily injection regimen:
 - i. Hgb A1C level is greater than 7.0%; **or**
 - ii. History of recurring hypoglycemia; **or**
 - iii. Wide fluctuations in blood glucose before mealtimes; **or**
 - iv. Dawn phenomenon with fasting blood sugars frequently exceeding 200mg/dL

OR

2. Pregnancy related conditions:
 - a. The patient has the onset of gestational diabetes and experiences erratic blood sugars despite maximal patient compliance; **or**
 - b. Pregnancy occurs in a previously diagnosed diabetic and the patient has erratic blood sugars despite maximal compliance; **or**
 - c. When pregnancy is anticipated within 3 months in the diagnosed diabetic **and** the patient has erratic blood sugar, ketoacidosis or symptomatic hypoglycemia despite maximal patient compliance

OR

3. Diabetic members with chronic renal failure and unstable diabetes who are not on renal dialysis

OR

4. The patient has an insulin pump and a replacement pump is required. A replacement pump will be authorized if the pump is past warranty and is not functioning properly.

Not Covered:

1. Insulin pump upgrades are not covered. Per manufacturer guidelines, pump upgrades are provided when the pump is still under warranty
2. ODS does not cover additional software or hardware required for downloading data to a personal computer to aid in diabetes self-management as it is considered a convenience item and not medically necessary.
3. The following types of insulin pumps are considered investigational and are not covered by ODS:

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- a. Fully implantable insulin pumps
- b. Chronic intermittent intravenous insulin therapy (CIIT) or pulsatile IV insulin therapy (PIVIT)

Information to be Submitted with Pre-Authorization Request:

1. Clinical records for the past 12 months.
2. Patient diary of blood sugar/insulin dosing for the prior 2-month period.
3. Laboratory Hgb A1C values

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