MILLE LACS BAND OF OJIBWE HEALTH AND HUMAN SERVICES POLICY & PROCEDURE

Department: Health Services – Diabetes Pro	ogram Policy Number: HHS-HS-DIA 1210
Policy Title: External Insulin Pump Policy	
Attachments:	
Revision History: new policy	Revised by/Date: Jackie Braun, 3/11/2021; Jenna Kuduk, 4/2021
Jan Manary, Executive Director of HHS	Date: 5.3. 202/
Jan Manary, Executive Director of HHS	
Approved by:	Date:
Nicole Anderson, Commissioner of HHS	5-4-2021

POLICY STATEMENT: The purpose of the insulin pump is to provide an accurate, continuous, controlled delivery of insulin which can be regulated by the user to achieve intensive glucose control objectives and to prevent the metabolic complications of hypoglycemia, hyperglycemia and diabetic ketoacidosis.

PURPOSE:

To define policy in the following area:

- Medical Description/Background
- Indications and eligibility for insulin pump therapy
- Limitations and Exclusions
- Replacement of external insulin pump or system component
- Replacement of lost, stolen or destroyed external insulin pump
- Continued coverage of an external insulin pump and supplies
- Discontinuation of Insulin Pump Therapy

PROCEDURE:

1. Medical Description/Background

External insulin pumps offer an alternative delivery method for subcutaneous insulin for the treatment of diabetes mellitus Type 1 and Type 2. Insulin pumps consist of a reservoir, a pump, and infusion set or pod. The reservoir typically contains a two to three day supply of insulin, which is delivered by a battery powered pump. The infusion set is comprised of tubing, which allows delivery of insulin, from the reservoir to a subcutaneously placed cannula. The cannula can be inserted in the abdomen, upper thigh, lower back, or upper arm. Insulin pumps require the infusion set and reservoir to be changed every two to three days. Insulin pumps can deliver rapid or short acting insulin 24 hours a day, consisting of basal rates, bolus doses to cover meals, and correction doses.

Requests that do not specially meet the criteria may be submitted with supporting medical records, article from the literature, etc. and will be reviewed by a physician for a medical exception.

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2. Indications and Eligibility for Insulin Pump Therapy

Insulin pump therapy requires appropriate patient selection, which is a critical factor for success. A thorough assessment of the patient's diabetes knowledge and management principles is recommended. Prospective pump users or caregivers must understand pump usage and must be able to troubleshoot problems. They must also be able to count carbohydrates and monitor blood glucose levels at least 4 times per day.

Patients must meet all of the following criteria:

- Insulin pumps must be ordered and managed by a medical provider, endocrinologist and/or diabetes specialist.
- The patient must have completed a diabetes self-management education program.
- The patient must require multiple daily injections of insulin (at least 3 insulin injections per day) for at least 6 month prior to initiation of insulin pump.
- The patient must test blood glucose levels at least 4 time per day in the 60 days prior to the request for an insulin pump.
- The patient must possess the ability to understand insulin pump technology and is able to take action based on glucose data interpretation.
- The member meets at least one of the supporting criteria for medical necessity:
 - Evidence of "inadequate glycemic control" as evidenced by HbA1c greater than a set target (A1c > 7%), episodes of persistent hyperglycemia (>180 mg/dL), or diabetic ketoacidosis despite compliance with adjustments in self-monitoring and insulin administration regimens.
 - Frequent and unpredictable wide fluctuations in blood glucose levels despite insulin adjustments.
 - O Documented recurring episodes of severe unexplained hypoglycemia (<50 mg/dL) and/or hypoglycemia unawareness).

3. Limitations and Exclusions

- Insulin pumps are not approved for convenience.
- Implantable insulin pumps are not covered.
- Nonprogrammable disposable insulin delivery systems will be evaluated on a case to case basis.

4. Replacement of External Insulin Pump or System Component

- The replacement of insulin pumps that are out of warranty, are malfunctioning, and/or cannot be refurbished is considered medically necessary. Clinical documentation will be required.
- Replacement insulin pumps with a continuous glucose monitor require clinical documentation including a blood glucose log to support medical necessity.
- Replacement of a functioning insulin pump with an insulin pump with additional software/hardware, such as a continuous glucose monitor, for the sole purpose of upgrading to the latest technology is not considered to be medically necessary.
- Replacement of insulin pumps under warranty is not a covered benefit unless considered medically necessary (e.g., child needing larger reservoir). Note: typical pump warranty is 4 years.
- Insulin pumps that are not FDA approved will not be considered.

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5. Replacement of lost, stolen or destroyed external insulin pump

- The Mille Lacs Band of Ojibwe Diabetes Program will replace one lost, stole or destroyed insulin pump per calendar year if not covered by an alternative entity (including but not limited to homeowners insurance and automobile insurance) if:
 - The insulin pump absence would put the member at risk of death, disability or significant negative health consequences such as a hospital admission.
 - o The insulin pump is still under warranty.

Note: In order to replace a stolen item, we require you to submit documentation, such as a police report, with the request.

6. Continued coverage of an external insulin pump and supplies

- Members require follow up care and evaluation by the treating physician at least every six months.
- Supplies are considered medically necessary and are provided through the MLBO Diabetes Program.

7. Discontinuation of Insulin Pump Therapy

The Mille Lacs Band of Ojibwe diabetes team will periodically assess the appropriateness of continuing insulin pump therapy, depending on adherence to necessary minimum standards of care. Where necessary, the team will make the recommendation to withdraw insulin pump therapy.

Criteria for Discontinuing Insulin Pump Therapy

- Patient or family choice
- Recurrent site problems leading to infection or skin trauma
- Psychological distress, despite appropriate support and advice
- Family/personal difficulties in providing safe pump management , or inability to ensure safe pump management
- Inadequate self-care
 - o Inadequate blood glucose tests
 - o Failure to respond to hyperglycemia with appropriate insulin administration
 - o Failure to manage carbohydrate intake with appropriate insulin administration
 - o Non-adherence with recommended care and/or clinic or other appointments including education
 - o Misuse of equipment
- Severe adverse events (e.g., episode of diabetic ketoacidosis, insulin overdose, intentional non-administration of insulin)
- Failure to improve glycemic control or episodes of severe hypoglycemia, despite all efforts of the diabetes team and patient/family.

Internal and/or External References	
Compliance - Posting Date	5/4/2021 1
Replaces – Policy Number	
Next Review - Due Date	5/4/2024