ILLINOIS DEPARTMENT OF Healthcare and Family Services

External Insulin Management System Prior Authorization Criteria

An External Insulin Management System (EIMS) is intended for subcutaneous delivery of insulin at set and variable rates for the management of diabetes mellitus in persons requiring insulin. The External Insulin Management System is a programmable system comprised of a wearable pod and a handheld device with a rechargeable battery that controls and monitors the pod's operations using wireless technology. The Pod is a lightweight device that you fill with insulin and wear directly on your body. It is applied to the skin with an adhesive, similar to a bandage and receives instructions on insulin delivery from the handheld device. Insulin is delivered from the Pod through a small, flexible cannula. The Pod is removed and a new one applied every 3 days as insertion sites are rotated. This allows delivery of a continuous subcutaneous insulin infusion in a more physiologic manner much like the pancreas. The Pods have programmable features that can be regulated by the user and include delivery of a steady basal infusion and bolus amounts at meals and intervals as needed.

Diabetes can be classified into four clinical categories:

- T1DM - due to beta (ß)-cell destruction usually leading to absolute insulin deficiency
- T2DM — due to progressive insulin secretory defect on the background of insulin resistance
- Gestational diabetes mellitus (GDM) — diabetes mellitus diagnosed during pregnancy that is not clearly overt diabetes
- Other specific types due to other causes (e.g., genetic defects in ß - cell function, genetic defects in insulin action, diseases of exocrine pancreatic function such as cystic fibrosis, and drug or chemical induced such as in treatment of HIV/AIDS or after organ transplantation).[1]

The presence of islet cell autoantibodies is strongly associated with the development of T1DM. The appearance of autoantibodies to one or several of the autoantigens signals an autoimmune pathogenesis of ß-cell killing. [2] Three-quarters of all cases of T1DM are diagnosed in individuals <18 years oid.[1]

Four of the most common diabetes related autoantibody tests are:

- Islet cell cytoplasmic autoantibodies (ICA)
- Glutamic acid decarboxylase autoantibodies (GADA)
- Insulinoma associated 2 autoantibodies (IA-2A)
- Insulin autoantibodies (IAA).

The goal of an External Insulin management System is to achieve intensive glycemic control to minimize the risk of metabolic complications (e.g., hypoglycemia, hyperglycemia, and ketoacidosis), macrovascular complications (e.g„ ischemic heart disease, peripheral vascular disease, and cerebrovascular disease), and microvascular complications (e.g., retinopathy, neuropathy, and nephropathy). Cardiovascular disease is increased two to threefold in diabetics. [I] This is the major cause of morbidity and mortality for diabetics and is the largest contributor to the direct and indirect costs related to diabetes.[1]

External Insulin Management Systems should only be ordered and managed by an endocrinologist/diabetologist or other clinician who certifies and possesses the necessary knowledge, skills, and experience managing multiple patients on these systems. This clinician must have available all of the resources to commit to and provide effective and safe initiation and maintenance of this therapy. The patient should have already undergone a comprehensive diabetes evaluation. The ordering clinician must be part of a multi-disciplinary team including a diabetic nurse, diabetic educator, and registered dietitian who can provide ongoing patient education, training, and close follow-up to ensure optimal use of the EIMS. Upon initiation of the EIMS the patient should have regular

contact with the system prescriber if necessary. Educational consultations should be scheduled weekly or biweekly at first and then periodically thereafter as needed. A follow-up appointment with the physician should occur 3-7 days after initiation of the EIMS and then monthly until the EIMS regimen is stabilized. Thereafter, follow-up should occur at least once every 3 months.

Selection of the appropriate patient for the External insulin Management System is critical to the eventual success of this therapy and applies to all groups discussed below. Adverse events may be directly related to improper patient selection and inadequate education. In addition to the specific criteria below the patient and/or caretakers in the case of pediatric patients must be motivated to achieve optimal blood glucose control and willing and able to carry out the tasks required to use this therapy. Patients should be emotionally mature and in a stable life situation. These candidates should receive training in carbohydrate counting, matching food, pre-meal blood glucose, and anticipated activity with insulin action and dose, and have knowledge how to calculate insulin correction doses. Patients and caretakers must be educated on the meaning of system alarms. They must have the knowledge and technical ability to handle emergencies and ability to make recommended dose changes out of the clinician's office. They must be willing to maintain frequent contact with the treating health care team and commit to long term follow-up.

The benefits of an External Insulin Management System in youth with T1DM have been documented and has been shown to be an effective means of optimizing glycemic control in very young patients with T1DM and may be superior to multiple daily injections (MDI) in minimizing risk of severe hypoglycemia. In fact infants, toddlers, and preschoolers are probably the ideal pediatric EIMS patient since it lowers the glycosylated hemoglobin AIC (HgbA1C) and reduces the frequency of severe hypoglycemic episodes.

An External Insulin Management System is a safe and effective option for maintaining glycemic control in pregnancies complicated by GDM/T2DM requiring large insulin doses.

Patients with the following characteristics are not good candidates for EIMS:

- Unwilling or unable to perform multiple daily injections (≥3-4 daily), frequent self monitoring of blood glucoses (SMBG) (≥4 times daily), and carbohydrate counting
- Lack of motivation to achieve tighter glucose control
- History of non-adherence to insulin injection protocols
- History of serious psychological or psychiatric conditions (e.g., psychosis, severe anxiety, or depression)
- Substantial reservations about Pod usage interfering with lifestyle (e.g., contact sports)
- Unrealistic expectations of EIMS therapy (e.g., belief that EIMS eliminates need to be responsible for diabetes management).

At the present time use of R U-500 insulin in External Insulin Management Systems is not approved by the FDA. This is considered experimental and investigational and will not be approved by this Department.

A request for an External Insulin Management System requires prior approval with submission of an HFS 3082 Prior Approval Request form with an order from an acceptable treating source. Typically, these requests will be approved with the initial approval spanning 3 months and the second approval period spanning 9 months during the first year and then yearly thereafter. The length of these approvals may be adjusted as dictated by clinical circumstances. The initial approval request must contain a completed HFS 1340 Prior Approval Request Form, Certificate of Medical Necessity for External Insulin Management System. The second prior approval request for continuation of the prior approval must contain a completed HFS 1345 Prior Approval Request Form, Certificate of Medical Necessity for Continuation of External Insulin Management System. The latter provides information about the clinical course of the patient since initiating EIMS therapy. In the event EIMS therapy fails to provide the patient with the expected benefit or if there are safety issues following a closely monitored initial trial, the clinician must be willing to terminate EIMS therapy and offer suitable alternatives. Patient suitability for Pod use must be re-examined, at minimum, annually.

The average expected lifespan of an External Insulin Delivery System is 4 years.

The following criteria (A., B., C., and D.) are oriented towards the patient with T1DM. An External Insulin Delivery System will be considered for approval for these patients if the following criterion A or B is met and if criterion C or D is met:

A. C-peptide testing to document insulinopenia (levels only need to be documented once in the medical record): must meet criterion 1 or 2 and criterion 3:

1. Fasting C-peptide <110% of the lower limit of the normal range for the testing laboratory's measurement method
2. For patients with renal insufficiency and creatinine clearance (actual or calculated from age, gender, height, weight, and serum creatinine) ≤50 mls/minute, a fasting C-peptide level ≤ 200% of the lower limit of the normal range for the testing laboratory's measurement method
3. The fasting blood glucose obtained concurrently with the C-peptide that is ≤225 mg/dl

B. Beta cell autoantibody test is positive (levels only need to be documented once in the medical record)

C. The patient must have completed all of the following:
- Comprehensive diabetes education program within the past 2 years
- A program of MDI (at least 3-4 injections per day) with frequent self adjustments of insulin dose for at least 6 months prior to initiation of the EIMS
- Documented frequency of SMBG on average ≥4 times per day during the 2 months prior to the initiation of EIMS
- And meets one or more of the following while on MDI of insulin and in spite of maximal patient compliance:
    1. HgbA1C >7% unless there is documented frequent hypoglycemia that contributes to an artificially low HgbA1C
    2. History of recurring severe symptomatic hypoglycemia (blood glucose <60 mg/dl) and/or glucagon administration on repeated occasions
    3. Hypoglycemic unawareness
    4. Wide fluctuations in blood glucoses before mealtimes
    5. Dawn phenomenon with fasting blood glucoses frequently exceeding 200 mg/dl
    6. History of severe glycemic excursions
    7. Recurrent diabetic ketoacidosis
    8. Treatment regimen that compromises lifestyle
    9. Erratic lifestyle (e.g., frequent long distance travel, shift work, unpredictable schedules leading to difficulty maintaining meal timing)
    10. Microvascular complications and/or risk factors for macrovascular complications
    11. Extreme insulin sensitivity.

D. The patient has previously and compliantly used an External Insulin Management System with documented improvement in glycemic control, continues to follow-up regularly with the treating source, and has been performing glucose self testing on average at least 4 times per day.

EIMS will be considered on an individual basis for other insulin dependent diabetics not meeting the above criteria when A., B., C., D., E., F., or G. of the following apply:

A. The patient must have completed all of the following:
- Comprehensive diabetes education program within the past 2 years
- A program of MDI (at least 3-4 injections per day) with frequent self adjustments of insulin dose for at least 6 months prior to initiation of the EIMS
- Documented frequency of SMBG on average ≥4 times per day during the 2 months prior to the initiation of EIMS
- And meets one or more of the following while on multiple daily insulin injections and in spite of maximal patient compliance:
    1. HgbA1 C>7% unless there is documented frequent hypoglycemia that contributes to an artificially low HgbA1 C
    2. History of recurring symptomatic hypoglycemia: blood glucose <60 mg/dl and/or glucagon administration on repeated occasions
    3. Hypoglycemic unawareness
    4. Wide fluctuations in blood glucoses before mealtimes
    5. Dawn phenomenon with fasting blood glucoses frequently exceeding 200 mg/dl
    6. History of severe glycemic excursions
    7. Recurrent diabetic ketoacidosis

8. Treatment regimen that compromises lifestyle
9. Erratic lifestyle (e.g., frequent long distance travel, shift work, unpredictable schedules leading to difficulty maintaining meal timing)
10. Microvascular complications and/or risk factors for macrovascular complications
11. Extreme insulin sensitivity.

B. Pregnancy: Selected diabetic women with exogenous insulin dependency who become pregnant or in whom pregnancy is anticipated within 3 months and pregnant teens ideally with Pod use initiated before conception.

C. Selected patients with other diabetes mellitus types (e.g., status post pancreatectomy)

D. Selected adolescent diabetic patients with eating disorders

E. Selected ketosis prone patients

F. Selected young children

G. The patient has previously and compliantly used an External Insulin Management System with documented improvement in glycemic control, continues to follow-up regularly with the treating source, and has been performing glucose self testing on average at least 4 times per day.

References

1. 1. American Diabetes Association. Standards of Medical Care in Diabetes — 2014. Diabetes Care. January 2014; 37 (supplement I):S14-S80.

2. Pihoker C, Gilliam L, Hampe C, Lernmark A. Autoantibodies in Diabetes. Diabetes. Dec 2005; 54(supplement 2): S52-S61.