TO BE RESCINDED

5160-10-29 **External insulin infusion pump.**

(A) Definition

A standard portable external insulin infusion pump is a small battery-operated pump about the size of a personal pager, is filled with insulin, and is connected to thin tubing ending in a needle. The needle is inserted into the skin around the abdomen, and supplies a regulated dose of insulin to the user for a day or more at a time. The pump may be carried in a pocket or in a case worn attached to a belt fastened around a consumer's waist.

(B) Coverage determination

(1) Ohio medicaid covers standard portable external insulin infusion pumps for patients with type 1 diabetes mellitus documented by a C-peptide level less than 0.5 and when all of the following medical necessity criteria are met:

(a) The consumer has completed a diabetes education program within the last twenty four months of being prescribed an insulin infusion pump;

(b) The consumer has been on a program of multiple daily injections of insulin (i.e., at least three injections per day), with frequent self-adjustments of insulin dose, for at least six months before initiation of the insulin infusion pump;

(c) The consumer had documented frequency that is kept in the consumer's medical record of glucose self-testing an average of at least four times per day during the two months before initiation of the insulin infusion pump;

(d) The consumer is at high risk for preventable complications of diabetes. Early signs of diabetic complications include micro-albuminuria and/ or documented in the consumer's medical record persistent difficulty in achieving optimal control of blood sugar levels despite good compliance with an intensive multiple injection regimen.

(2) In addition to the aforementioned criteria, the consumer needs to meet at least one of the following criteria in order to be eligible for a standard portable external insulin infusion pump:

(a) Glycated hemoglobin level (HbA1c) greater than seven per cent;

(b) History of recurring hypoglycemia;

(c) Wide fluctuations in blood glucose before mealtime;

(d) Dawn phenomenon with fasting blood sugars frequently exceeding two hundred mg/dL; or

(e) History of severe glycemic excursions.

(C) Non-coverage determination

(1) Standard portable external insulin infusion pumps are not covered if any of the following contraindications exist:

(a) Consumer has non-insulin dependent (NIDDM or IR-NIDDM, Type II) diabetes, even if insulin is taken;

(b) Consumer has end-stage complications such as renal failure;

(c) Consumer is unable, because of behavioral, psychological problems or functional ability, to technically operate the pump and perform frequent blood glucose monitoring; or

(d) Consumer is being prescribed pump therapy to be used for convenience purposes.

(2) The department will not cover jet pressure or surgically implanted infusion devices or systems, chronic intermittent intravenous insulin therapy (CIIIT), or pulsatile IV insulin therapy (PIVIT).

(D) Prior authorization

(1) The following documentation must be submitted for prior authorization (PA) before reimbursement for a standard portable external insulin infusion pump will be considered:

A fully completed form JFS 07136 (rev. 3/2008) "Certificate of Medical Necessity/Prescription External Infusion Pump" (CMN) (appendix to this rule) that is signed and dated no more than thirty days before the first date of service.

(2) Prior authorization for a standard portable external insulin infusion pump must include a three-month trial rental period conducted in which the consumer has undergone a successful trial period with a pump that demonstrates that the consumer is capable of managing the pump and that the desired improvement in metabolic control can be achieved. If a prescriber certification is submitted to the department at the conclusion of a successful trial rental period, the device

will be considered for purchase by the department in accordance with paragraph (I) of rule 5101:3-10-05 of the Administrative Code.

(E) Dispensing

(1) The following components are considered "inclusive" with any portable external infusion insulin pump rental or purchase payment made by the department on behalf of a consumer and cannot be submitted to the department for separate reimbursement:

(a) Any supporting wires, power supply, cables, attachment kits, or disposable items associated with the operation of the pump;

(b) Pump education, training, monitoring, or counseling in support of the consumer's ordered treatment;

(c) Maintenance, repair, or cleaning charges in association with the three-month trial rental period; or

(d) Delivery, set-up, or pick-up charges.

(2) The provider of the portable external infusion insulin pump must assure that the consumer utilizing the device is properly instructed on how to use the device in support of his or her ordered treatment and is aware of and understands any emergency procedures regarding the use of the pump. The provider must maintain written documentation regarding the consumer's instruction on the use of the pump in the provider's records.

(3) The prescriber of the portable external infusion insulin pump must assure and document in the consumer's medical record that the continued use of the device is resulting in the clinical improvement of the consumer utilizing the device. The use of the device must be discontinued immediately and an alternative treatment method considered if the consumer demonstrates no progressive clinical improvement during the rental period of the device.

(4) When the department determines that the purchase of a portable external infusion insulin pump is appropriate, the consumer must be provided with a product warranty that covers any required maintenance or repairs for a duration of at least one year and commences on the date the infusion pump was authorized for purchase.

(F) Reimbursement

(1) Portable external infusion insulin pumps are reimbursed according to the department fee schedule contained in appendix DD to rule 5101:3-1-60 of the Administrative Code or the providers' usual and customary charges, whichever is less.

(2) Previously utilized or loaner portable external infusion insulin pumps are not eligible for purchase by the department.

Effective:

Five Year Review (FYR) Dates: 4/27/2018

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Certification

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Date

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