5160-10-29 **DMEPOS: insulin pumps.**

(A) Definitions.

(1) "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.

(2) "Insulin pump," for purposes of this rule, is a collective term encompassing a portable external insulin infusion pump and a sensor-augmented insulin pump system.

(B) Coverage.

(1) Payment may be made for a portable external insulin infusion pump on a rental/purchase basis. The initial rental period is limited to three months.

(2) The default certificate of medical necessity (CMN) form is the ODM 07136, "Certificate of Medical Necessity: Insulin Pumps" (rev. 7/2018). The CMN must include an attestation that appropriate documentation is kept in the individual's medical record to demonstrate that the following criteria are met:

(a) The individual has type 1 diabetes mellitus;

(b) The individual has at least one of the following symptoms or conditions:

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

(ii) A history of recurring hypoglycemia;

(iii) Wide fluctuations in blood glucose before mealtime;

(iv) A marked early-morning increase in fasting blood sugar (the "dawn phenomenon"), in which the glucose level frequently exceeds two hundred milligrams per deciliter; or

(v) A history of severe glycemic excursions;

(c) The individual has completed a diabetes education program within the preceding twenty-four months;

(d) The individual has been on a maintenance program for at least six months involving at least three injections of insulin per day and frequent self-adjustments of insulin dosage;

(e) The individual has performed glucose self-testing at least four times per day on average during the preceding month; and

(f) The individual is at high risk for preventable complications of diabetes, early signs of which include micro-albuminuria and persistent difficulty in controlling blood sugar levels despite good compliance with an intensive multiple-injection regimen.

(3) After the first three months, payment may be made for the purchase of an insulin pump. During the initial rental period, the provider must obtain a revised copy of the previously completed CMN, on which the prescriber attests that the individual (or someone assisting the individual) is capable of managing the pump and that the desired improvement in metabolic control can be achieved.

(C) Requirements, constraints, and limitations.

(1) The use of an insulin pump is contraindicated by any of the following conditions or circumstances:

(a) The individual has type 2 (non-insulin-dependent) diabetes mellitus, either treated or not treated with insulin;

(b) The individual has end-stage complications such as renal failure; or

(c) Neither the individual nor anyone assisting the individual is able to operate a pump or to perform frequent blood glucose monitoring.

(2) The following insulin-delivery devices are not covered:

(a) A portable external insulin infusion pump that is requested purely as a matter of convenience or individual preference;

(b) Surgically implanted infusion devices or systems;

(c) Jet pressure devices;

(d) Devices associated with chronic intermittent intravenous insulin therapy (CIIIT), or

(e) Devices associated with pulsatile intravenous insulin therapy (PIVIT).

(3) The warranty period for a covered insulin pump is at least one year from the date of purchase authorization.

(4) No payment may be made for the purchase of an insulin pump that has been previously used by another individual.

Replaces: 5160-10-29

Effective:

Five Year Review (FYR) Dates:

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Certification

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Date

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