MEDICAL POLICY

Excellus

SUBJECT: EXTERNAL INSULIN PUMP THERAPY FOR DIABETES	EFFECTIVE DATE: 11/19/99 REVISED DATE: 12/07/00, 06/20/01, 06/20/02, 08/28/03, 10/28/04, 02/02/05, 12/01/05, 02/22/07, 12/13/07, 12/11/08, 10/28/09, 10/28/10, 12/08/11, 10/25/12, 12/12/13
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- ***If the member's subscriber contract excludes coverage for a specific service it is not covered under that contract. In such cases, medical policy criteria are not applied.***
- ***Medical policies apply to commercial and Medicaid products only when a contract benefit for the specific service exists.***
- ***Medical policies only apply to Medicare products when a contract benefit exists and where there are no National or Local Medicare coverage decisions for the specific service.***

POLICY STATEMENT:

I. Based upon our criteria and review of the peer-reviewed literature, basic external insulin pumps are **medically appropriate** when the patient:
   A. has completed a comprehensive diabetes education program, and
   B. has been on a program of multiple daily injections of insulin (at least 3 per day), with frequent self-adjustments of insulin dose for at least 6 months prior to initiation of the insulin pump, and
   C. has documented frequency of glucose self-testing an average of at least 4 times per day during the 2 months prior to initiation of the insulin pump, and
   D. meets one or more of the following criteria while on the multiple injection regimen:
      1. HbA_{1C} greater than 7% within the last four months,
      2. History of recurring hypoglycemia,
      3. Wide fluctuations in blood glucose before mealtime,
      4. Dawn phenomenon with fasting blood sugars frequently exceeding 200 mg/dL, or
      5. History of severe glycemic excursions.

II. Insulin pump therapy is **medically appropriate** for women with gestational diabetes who:
   1. Require insulin injections greater than or equal to 3 times per day; and
   2. Who cannot be controlled by intermittent dosing.

III. Based upon our criteria and review of the peer-reviewed literature, insulin pump therapy, as the initial treatment for insulin dependent diabetic patients without an adequate trial of conventional insulin therapy with multiple daily injections of insulin is **not medically appropriate**.

IV. Based upon our criteria and review of the peer-reviewed literature, sensor-augmented insulin pump therapy with the low glucose threshold suspend feature (e.g, Minimed® 530G system with Enlite®, Medtronic, Inc) is considered **medically necessary** in children and adults 16 years and older when the criteria for external insulin pumps and continuous glucose monitors has been met.

V. Based upon our criteria and review of the peer-reviewed literature, sensor-augmented insulin pump therapy with the low glucose threshold suspend feature (e.g, Minimed® 530G system with Enlite®, Medtronic, Inc) is considered **investigational** in children younger than 16 years.

VI. Replacement of an insulin pump is considered **medically necessary** when:
   A. the pump has exceeded the warranty time period; AND
   B. the pump is malfunctioning.

VII. Replacement due to slight damage to the pump without causing the pump to malfunction or replacement desired due to advanced technology is considered **not medically necessary**.

Refer to Corporate Medical Policy #1.01.30 regarding Continuous Glucose Monitoring Systems

POLICY GUIDELINES:

I. Only basic insulin pump models are **medically necessary**. The patient is liable for any non-medical accessories or add-ons.

II. Replacement of purchased equipment which is damaged due to patient neglect, theft, abuse, or when another available coverage source is an option (e.g., homeowners, rental, auto, liability insurance, etc.) is **ineligible for coverage**.

DESCRIPTION:

External insulin pumps are utilized by diabetic patients for continuous subcutaneous insulin infusion (CSII) and who are unable to control their diabetes with multiple daily insulin injections. The pump contains an insulin filled cartridge or syringe connected to a catheter that is inserted into the patient's subcutaneous tissue, usually in the abdomen. After programming, the pump continuously delivers a predetermined amount of insulin to meet the patient's insulin requirements. The devices allow programming of different basal and bolus infusion rates, as needed.

CSII provides superior glycemic control over manual daily injections of insulin, decreases the frequency and/or severity of hypoglycemic reactions, and increases lifestyle flexibility.

Recently the FDA has approved the MiniMed 530G System which consists of the following devices that can be used in combination or individually: MiniMed 530G Insulin Pump, Enlite™ Sensor, Enlite™ Serter, the MiniLink Real-Time System, the Bayer Contour NextLink glucose meter, CareLink® Pro Therapy Management Software for Diabetes, and CareLink® Personal Therapy Management Software for Diabetes. The system requires a prescription. The MiniMed 530G System is not intended to be used directly for making therapy adjustments, but rather to provide an indication of when a finger stick may be required. The MiniMed 530G System is not intended to be used directly for preventing or treating hypoglycemia but to suspend insulin delivery when the user is unable to respond to the Threshold Suspend alarm to take measures to prevent or treat hypoglycemia himself. Continued approval of this device is contingent upon the submission of periodic reports, in order to provide continued reasonable assurance of the safety and effectiveness of the device.

New York State Law mandates coverage of insulin pumps under health care contracts that provide major medical or similar comprehensive-type coverage for the treatment of diabetes, if recommended or prescribed by a physician or other licensed health care provider legally authorized to prescribe such devices under the New York State Education Law.

CODES: Number Description

Eligibility for reimbursement is based upon the benefits set forth in the member's subscriber contract.

CODES MAY NOT BE COVERED UNDER ALL CIRCUMSTANCES. PLEASE READ THE POLICY AND GUIDELINES STATEMENTS CAREFULLY.

Codes may not be all inclusive as the AMA and CMS code updates may occur more frequently than policy updates.

CPT: No code(s)

HCPCS:	A4230	Infusion set for external insulin pump, nonneedle cannula type
	A4231	Infusion set for external insulin pump, needle type
	A4232	Syringe with needle for external insulin pump, sterile, 3 cc
	A9274	External ambulatory insulin delivery system, disposable, each, includes all supplies and accessories

	E0784	External ambulatory infusion pump, insulin
	S9145	Insulin pump initiation, instruction in initial use of pump (pump not included)
ICD9:	250-250.93	Diabetes Mellitus (code range)
	648.0-648.04	Gestational diabetes (code range)
ICD10:	E10.10-E10.9	Type 1 diabetes mellitus (code range)
	E11.00-E11.9	Type 2 diabetes mellitus (code range)
	E13.00-E13.9	Other specified diabetes mellitus (code range)
	O24.011-O24.019	Pre-existing diabetes mellitus, type 1, in pregnancy (code range)
	O24.03	Pre-existing diabetes mellitus, type 1, in the puerperium
	O24.111-O24.119	Pre-existing diabetes mellitus, type 2, in pregnancy (code range)
	O24.13	Pre-existing diabetes mellitus, type 2, in the puerperium
	O24.311-O24.33	Unspecified pre-existing diabetes mellitus in pregnancy, childbirth and the puerperium (code range)
	O24.811-O24.819	Other pre-existing diabetes mellitus in pregnancy (code range)
	O24.83	Other pre-existing diabetes mellitus in the puerperium
	O24.911-O24.93	Unspecified diabetes mellitus in pregnancy, childbirth and the puerperium (code range)

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KEY WORDS:

Continuous subcutaneous insulin infusion, CSII, Insulin pump therapy.

CMS COVERAGE FOR MEDICARE PRODUCT MEMBERS

There is currently a National Coverage Determination (NCD) for Infusion Pumps. Please refer to the following NCD website for Medicare Members: https://www.cms.gov/medicare-coverage-database/details/ncd-details.aspx?NCDId=223&ncdver=2&bc=AgAAgAAAAAAA&