• If a product excludes coverage for a service, it is not covered, and medical policy criteria do not apply.
• If a commercial product, including an Essential Plan product, covers a specific service, medical policy criteria apply to the benefit.
• If a Medicare product covers a specific service, and there is no national or local Medicare coverage decision for the service, medical policy criteria apply to the benefit.

**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. HbA1C 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, the artificial pancreas system, which consists of sensor-augmented insulin pump therapy with the low glucose threshold suspend feature (e.g., Minimed® 530G system or 630G with SmartGuard™) and a continuous glucose monitor (Enlite®, Medtronic, Inc), is considered **medically necessary** for individuals 16 years and older when the criteria for both an external insulin pump and a continuous glucose monitor have been met.

V. Based upon our criteria and review of the peer-reviewed literature, the sensor-augmented insulin pump (e.g., Minimed® 530G or Minimed® 630G with SmartGuard™) as a stand-alone device is considered **medically appropriate** when the criteria for an external insulin pump have been met. **NOTE:** Approval of a sensor-augmented insulin pump does not constitute (nor guarantee) approval for a continuous glucose monitor system at a later date.

VI. 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 or 630G with SmartGuard™-with Enlite®, Medtronic, Inc) is considered **investigational** in children younger than 16 years.

VII. Based upon our criteria and review of the peer-reviewed literature, nonprogrammable disposable insulin delivery systems (e.g., V-Go™ disposable insulin delivery device) are considered **investigational**.
VIII. 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.

IX. 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) 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.

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. The MiniMed 530G System was approved by the FDA for use by people with diabetes ages 16 and older. In August 2016, the FDA approved the Minimed 630G System with Smartguard™, which consists of the Minimed 630G insulin pump as well as the Enlite® Sensor, One-press Serter, Guardian® Link Transmitter System, CareLink® USB, Bayer’s CONTOUR® NEXT LINK 2.4 Wireless Meter, and Bayer’s CONTOUR® NEXT LINK Test Strips. The MiniMed 630G System was approved by the FDA for use by people with diabetes ages 16 and older.

V-Go® (Veritas, Inc, Bridgewater,NJ)) is a disposable wearable device that delivers a continuous preset basal rate of insulin over 24 hours as well as on-demand bolus dosing at mealtimes for adults with Type 2 diabetes. V-Go can deliver insulin via two mechanisms; through a spring-activated mechanism which delivers insulin at a continuous preset basal rate and by a manual activation to deliver a bolus at mealtimes. Three options are available depending on the total continuous preset basal rate during a 24-hour period. Adverse reactions to the V-Go insulin delivery system include skin irritation from the adhesive pad or infections at the infusion site. V-Go should be removed before any magnetic resonance imaging (MRI) testing.
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:

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)

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HCPCS:

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<tr>
<th>Code</th>
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<tr>
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<tr>
<td>A4232</td>
<td>Syringe with needle for external insulin pump, sterile, 3 cc</td>
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<td>A9274</td>
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<td>E0784</td>
<td>External ambulatory infusion pump, insulin</td>
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<td>S1036</td>
<td>Transmitter; external, for use with artificial pancreas device system</td>
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<td>S1037</td>
<td>Receiver (monitor); external, for use with artificial pancreas device system</td>
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<td>S9145</td>
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<td>Gestational diabetes (code range)</td>
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<td>Other specified diabetes mellitus (code range)</td>
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<td>Pre-existing diabetes mellitus, type 2, in pregnancy (code range)</td>
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<td>O24.311-O24.33</td>
<td>Unspecified pre-existing diabetes mellitus in pregnancy, childbirth and the puerperium (code range)</td>
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</table>
REFERENCES:


New York State Consolidated Insurance Law. Article 43. § 4303.


**KEY WORDS:** Continuous subcutaneous insulin infusion, CSII, Insulin pump therapy.

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**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&.