Overview
The purpose of this document is to describe the guidelines AllWays Health Partners utilizes to determine medical necessity for insulin pumps. AllWays Health Partners will use this policy for utilization review purposes and may deny or limit services if they do not find the requests to be medically necessary.

Coverage Guidelines
As of February 20, 2017, medical necessity for insulin pumps is determined through InterQual® criteria. To access the criteria, log in to AllWays Health Partners’ provider website at allwaysprovider.org and click the InterQual® Criteria Lookup link under the Resources Menu. AllWays Health Partners covers diabetic insulin pumps for individuals when it is recommended by the member’s providers and when the request meets the medical necessity criteria. In addition, the member’s endocrinologist is responsible for providing all necessary clinical information for the determination of medical necessity including: medical history, diabetes education received, treatment to date, glucose reading logs, pertinent laboratory testing, treatment plan, and medical necessity rational. The treating endocrinologist must sign a prescription for any requested insulin pump/supply at least yearly.

Insulin Pump - Exclusions
1. Transdermal insulin delivery systems (e.g. V-Go) due to limited data to support use over alternatives.
2. Replacement or repair of an insulin pump when:
   a. It is lost, stolen or damaged due to improper care, or misuse, or neglect (AllWays Health Partners may require proof of the stolen or damaged item. Proof consists of a police report, pictures or corroborating statement);
   b. The member has a functioning model and a newer or upgraded model is not medically necessary;
3. Devices or device features that are to be principally used for convenience and are not medically necessary
4. Devices or device features that are considered experimental and investigational.

Definitions
Continuous Glucose Monitors: Minimally invasive or noninvasive devices that measure glucose levels in the interstitial fluid surrounding skin cells over a short-term period of several days or for long-term use to provide continuous information about glucose fluctuations that is not otherwise captured by intermittent testing. The continuous glucose monitoring systems measure blood glucose with minimal invasiveness.
through continuous measurement of interstitial fluid (ISF) with a subcutaneously implanted sensor. These devices may require calibration with fingerstick testing. Several CGMS have been approved by the FDA. In addition to stand-alone continuous glucose monitors, several insulin pump systems have included a built-in continuous glucose monitor. Continuous glucose monitoring (CGM) in conjunction with intensive insulin regimens can be a useful tool to lower hemoglobin A1C levels in highly selected patients.

**Glycated hemoglobin:** Also known as HbA1c, is a form of hemoglobin. (Hemoglobin is the iron rich protein in red blood cells that gives blood its red color.) In the normal 120-day life span of a red blood cell, glucose molecules react with hemoglobin forming glycated hemoglobin. Individuals with diabetes have higher quantities of glucose in their capillary blood and as a result they also have increased numbers of glycated hemoglobin molecules. The 2018/2019 American Diabetes Association Standards of Medical Care include an HbA1c level $\geq 6.5\%$ as one of the criteria for diagnosing diabetes. Once a hemoglobin molecule is glycated, it remains that way. A build-up of glycated hemoglobin within the red blood cells therefore reflects the average level of glucose to which the cell has been exposed during its life cycle. Measuring glycated hemoglobin assesses the effectiveness of therapy for the treatment of diabetes.

**Hypoglycemia:** The International Hypoglycemia Study Group recommended a blood glucose value of 70 mg/dL or less as sufficiently low for treatment with fast-acting carbohydrates and less than 54 should be considered serious, clinically significant hypoglycemia. Severe hypoglycemia is defined as severe cognitive impairment requiring assistance from another person for recovery.

**External insulin pump:** An external insulin pump is a computerized, battery-powered device with programming capabilities that delivers insulin subcutaneously. The insulin is delivered in a programmed and controlled manner and eliminates the need for the patient to self-inject insulin. The main goal in using an insulin pump is to achieve near-normal blood glucose levels in order to prevent both acute and chronic complications of diabetes.

**Optimum Glycemic Control per ADA 2018/2019:**
- Lowering A1C for nonpregnant adults to $< 7\%$ to reduce microvascular and neuropathic complications of diabetes and, possibly, macrovascular disease.
- Lowering A1C for a selected individual adult to $<6.5\%$ without causing significant hypoglycemia or other adverse effects of treatment.
- Less stringent A1C goals (e.g. $<8\%$) may be appropriate for an adult patient with a history of: severe hypoglycemia, limited life expectancies, advanced microvascular or macrovascular complications, extensive comorbid conditions, or those with longstanding diabetes in whom the general goal is difficult to obtain despite education, monitoring and appropriate medications.
- Lowering A1C for children to $< 7.5\%$ with special consideration for the unique risks of hypoglycemia in very young children.

**CPT/HCPCS Codes**

<table>
<thead>
<tr>
<th>Authorized CPT/HCPCS Codes</th>
<th>Code Description</th>
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<tbody>
<tr>
<td>A4230</td>
<td>Infusion set for external insulin pump, non-needle cannula type</td>
</tr>
<tr>
<td>A4231</td>
<td>Infusion set for external insulin pump, needle type</td>
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399 Revolution Drive, Suite B10, Somerville, MA 02145 | allwayshealthpartners.org
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

Related Policies
• Continuous Glucose Monitors

Effective
December 2019: Annual update. Prior authorization requirement removed from table 1 on page 1.
Removed exclusion referencing pulsatile intravenous insulin therapy. Definitions and References updated.
December 2018: Annual update
April 2018: Added codes.
November 2017: Annual update.
February 2017: McKesson’s InterQual® criteria replaced the criteria as indicated in the policy.
July 2016: Annual update
July 2015: Effective date

References


International Hypoglycemia Study Group. Glucose concentration of less than 3.0 mmol/L (54 mg/dL) should be reported in clinical trials: a joint position statement of the ADA and EASD. Diabetes Care 2017; 40:155-157.


