Medical Policy
Insulin Pumps

Policy Number: 030

<table>
<thead>
<tr>
<th>Authorization required</th>
<th>Commercial and Qualified Health Plans</th>
<th>MassHealth</th>
</tr>
</thead>
<tbody>
<tr>
<td>Insulin Pumps &amp; Supplies</td>
<td></td>
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</tr>
<tr>
<td>No Prior Authorization</td>
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</table>

Overview
The purpose of this document is to describe the guidelines Mass General Brigham Health Plan utilizes to determine medical necessity for insulin pumps.

Prior authorization is currently not required for insulin pumps. For information regarding Mass General Brigham Health Plan’s Insulin Pumps, Artificial Pancreas Device System and Continuous Glucose Monitors medical policies, log in to Mass General Brigham Health Plan’s provider website at MassGeneralBrighamHealthPlan.org and click the InterQual® Criteria Lookup link under the Resources Menu.

Coverage Guidelines
Medical necessity for insulin pumps is determined through InterQual® criteria. Mass General Brigham Health Plan covers diabetic insulin pumps for individuals when it is recommended by the member’s providers. Clinical information used for medical necessity includes the following:

- Medical history;
- Diabetes education received;
- Treatment to date;
- Glucose reading logs;
- Pertinent laboratory testing;
- Treatment plan

The treating endocrinologist must sign a prescription for any requested insulin pump/supply at least yearly.

MassHealth
For MassHealth medical necessity authorization guidelines, including additional qualifying diagnoses or co-morbidities, please refer to the latest MassHealth Guidelines for Medical Necessity Determination for Diabetes Management Devices: Continuous Glucose Monitoring Systems and Insulin Pumps.

Insulin Pump - Exclusions
1. Transdermal insulin delivery systems (eg. V-Go) are excluded from the Mass General Brigham Health Plan medical benefit plans. As these devices are self-use, they may be covered under Mass General Brigham Health Plan Pharmacy benefit plan.
2. Replacement or repair of an insulin pump when:
   a. It is lost, stolen or damaged due to improper care, or misuse, or neglect (Mass General Brigham Health Plan 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 >/= 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 < or about 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.

Codes

<table>
<thead>
<tr>
<th>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>
</tr>
<tr>
<td>A4232</td>
<td>Syringe with needle for external insulin pump, sterile, 3 cc</td>
</tr>
<tr>
<td>Code</td>
<td>Description</td>
</tr>
<tr>
<td>--------</td>
<td>-----------------------------------------------------------------------------</td>
</tr>
<tr>
<td>A9274</td>
<td>External ambulatory insulin delivery system, disposable, each, includes all supplies and accessories</td>
</tr>
<tr>
<td>E0784</td>
<td>External ambulatory infusion pump, insulin</td>
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</table>

**Related Policies**

- [Continuous Glucose Monitors](#)

**Effective**


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.

Massachusetts State Mandate, General Laws Part I Title XXII Chapter 175 Section 47N: Items medically necessary for diagnosis and Treatment of Diabetes.


