Mass General Brigham
Health Plan

Medical Policy
Insulin Pumps

Policy Number: 030

	Commercial and Qualified Health Plans	MassHealth	Medicare Advantage
Authorization required Insulin Pumps & Supplies			
No Prior Authorization	X	X	X

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 into 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.

Insulin Pump Exclusions

1. Transdermal insulin delivery systems (e.g., 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.

MassHealth Variation

Mass General Brigham Health Plan uses guidance from MassHealth for coverage determinations for members of the MGB ACO. **As of Mass General Brigham Health Plan's most recent policy review, MassHealth had Guidelines for Medical Necessity Determination for Diabetes Management Devices: Continuous Glucose Monitoring Systems and Insulin Pumps.**

Medicare Variation

Mass General Brigham Health Plan uses guidance from the Centers for Medicare and Medicaid Services (CMS) for coverage determinations for its Medicare Advantage plan members. National Coverage Determinations (NCDs), Local Coverage Determinations (LCDs), Local Coverage Articles (LCAs) and documentation included in

the Medicare manuals are the basis for coverage determinations. When there is no guidance from CMS for the requested service, Mass General Brigham Health Plan's medical policies are used for coverage determinations. At the time of Mass General Brigham Health Plan's most recent policy review, Medicare includes coverage guidelines for the following:

- **LCD: External Infusion Pumps (L33794)**
- **LCA: External Infusion Pumps - Policy Article A52507**

Codes

The following codes are included below for informational purposes only; inclusion of a code does not constitute or imply coverage.

This list of codes applies to commercial and MassHealth plans only.

CPT/HCPCS Codes	Code Description
A4230	Infusion set for external insulin pump, non-needle 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

Related Policies

- Continuous Glucose Monitors

Effective

December 2024: Annual update. Added MassHealth Variation. Added policy article to Medicare Variation.
December 2023: Annual update. Medicare Advantage added to table 1. Medicare Variation language added. References updated.
January 2023: Annual update. Under Overview section, added insulin pumps. Under Coverage Guidelines section, MassHealth statement section added.
December 2021: Annual update. References updated.
January 2021: Annual update. Overview, Coverage Guidelines, and Exclusion sections revised for clarity purposes. Criteria requirements unchanged.
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.

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