

## Insulin Pumps - External

**Policy Number:**

MM.01.004

**Line(s) of Business:**

HMO; PPO; QUEST Integration

**Section:**

DME

**Place(s) of Service:**

Home

**Original Effective Date:**

04/01/2011

**Current Effective Date:**

08/29/2018

### I. Description

An external insulin infusion pump is a programmable, battery-powered mechanical syringe/reservoir device that is controlled by a micro-computer to provide continuous subcutaneous insulin infusion (CSII) to patients with diabetes mellitus who are insulinopenic. The pump delivers a steady "basal" amount of insulin and releases a bolus dose at meals or smaller amounts at programmed times. Frequent monitoring of the blood glucose (e.g., four times per day) is essential to ensure appropriate delivery of insulin dosage.

Some insulin pump systems include a continuous glucose monitoring system (CGMS). This policy addresses insulin pumps, not the CGMS component of these systems. For criteria/guidelines regarding CGMS, see HMSA's [Continuous Glucose Monitoring System](#) medical policy.

### II. Criteria/Guidelines

- A. An external insulin pump (E0784 and S1034) is covered (subject to Limitations and Administrative Guidelines) for patients with diabetes when all of the following criteria are met:
1. The insulin pump is ordered and follow-up care will be provided by an endocrinologist or in the absence of an endocrinologist, by a physician or a licensed healthcare practitioner who manages multiple patients on CSII therapy and who works closely with a team of health care providers, including a nurse, diabetic educator and/or dietician who are knowledgeable in the use of CSII.
  2. The patient or caregiver has completed a comprehensive diabetes self-management education program, including instruction in carbohydrate counting.
  3. The patient or caregiver has demonstrated compliance and competence with an intensive insulin regimen for at least three months prior to the request for the insulin pump, including the following:
    - a. Multiple daily injections of insulin i.e., at least three injections per day, with frequent self-adjustments of insulin dose based on glucose measurement and carbohydrate count and/or content of a meal.
    - b. Glucose self-testing an average of at least three times per day.

4. The patient has suboptimal control of diabetes despite competence and compliance with an intensive insulin regimen. Examples of suboptimal control include (but are not necessarily limited to) the following:
  - a. Glycosylated hemoglobin level (HbA1c) greater than seven percent
  - b. Repeated and unpredictable hypoglycemia
  - c. Wide fluctuations in preprandial blood glucose
  - d. Dawn phenomenon with fasting blood sugars frequently exceeding 200 mg/dl
  - e. Severe glycemic excursions
- B. Use of a disposable external insulin pump (A9274) with wireless communication capability to a hand-held control unit (e.g., Omnipod) as an alternative to a standard insulin pump is covered (subject to Limitations and Administrative Guidelines) for patients with diabetes when all of the above criteria are met.
- C. Supplies used with an insulin pump are covered when coverage criteria for the insulin pump are met.
- D. Replacement of an external insulin pump is covered (subject to Limitations and Administrative Guidelines) when the following criteria are met:
  1. Documentation from the patient's medical record supports that the pump is malfunctioning, out of warranty and cannot be repaired; or
  2. Documentation from the patient's medical record supports that a pump with newer technology or special feature is medically necessary.AND
  3. The replacement is ordered by the treating physician.
  4. The patient continues to use the pump and benefit from its use.

### III. Limitations

- A. Replacement of an insulin pump for the sole purpose of receiving an upgrade in technology is not covered.
- B. Replacement due to damage to the pump that does not cause the pump to malfunction is not covered.
- C. Supplies used with an insulin pump are not covered when coverage criteria for the insulin pump are not met.
- D. Transdermal insulin delivery system, e.g., V-Go Disposable Insulin Delivery Device, is not covered because it is not known to be effective in improving health outcomes.

### IV. Administrative Guidelines

- A. Precertification is required for initial and replacement insulin pumps. To precertify, complete HMSA's [Precertification Request](#) and mail or fax the form or use [iExchange](#).
- B. If HMSA's Precertification Request form is used, medical record documentation supporting the following must be submitted:
  1. Initial insulin pump:
    - a. The patient has completed a comprehensive diabetes self-management education program, including carbohydrate counting.

- b. The patient has been on an intensive insulin regimen for at least three months preceding the request.
- c. The patient has suboptimal control of diabetes despite being on an intensive insulin regimen.
- d. Results of HbA1c obtained within three months of the request.
- 2. Replacement insulin pump:
  - a. The pump is malfunctioning and out of warranty or that new technology is medically necessary.
  - b. The patient has continued to use the pump and benefit from its use.
  - c. Results of HbA1c obtained within three months of the request.
- C. If iExchange is used and even if Auto Approved, documentation supporting medical necessity must be kept in the patient’s medical records and be made available to HMSA upon request. HMSA reserves the right to perform retrospective review using the above criteria to validate if services rendered met payment determination criteria.

<b>HCPCS Codes</b>	<b>Description</b>
E0784	External ambulatory infusion pump, insulin
A9274	External Ambulatory Insulin Delivery, disposable, each, includes all supplies and accessories
S1034	Artificial pancreas device system (e.g., low glucose suspend [LGS] feature) including continuous glucose monitor, blood glucose device, insulin pump and computer algorithm that communicates with all the devices

**V. Important Reminder**

The purpose of this Medical Policy is to provide a guide to coverage. This Medical Policy is not intended to dictate to providers how to practice medicine. Nothing in this Medical Policy is intended to discourage or prohibit providing other medical advice or treatment deemed appropriate by the treating physician.

Benefit determinations are subject to applicable member contract language. To the extent there are any conflicts between these guidelines and the contract language, the contract language will control.

This Medical Policy has been developed through consideration of the medical necessity criteria under Hawaii’s Patients’ Bill of Rights and Responsibilities Act (Hawaii Revised Statutes §432E-1.4), generally accepted standards of medical practice and review of medical literature and government approval status. HMSA has determined that services not covered under this Medical Policy will not be medically necessary under Hawaii law in most cases. If a treating physician disagrees with HMSA’s determination as to medical necessity in a given case, the physician may request that HMSA reconsider the application of the medical necessity criteria to the case at issue in light of any supporting documentation.

## VI. References

1. National Institute for Health and Clinical Excellence (NICE). Continuous subcutaneous insulin infusion for the treatment of diabetes mellitus. London (UK): 2008 Jul. 30 p. (Technology appraisal guidance; no.151). Updated September 2014.
2. Noridian Administrative Services. Local Coverage Determination (LCD): External Infusion Pumps (L33794). Revision effective date 1/1/2017.
3. Handelsman Y, Bloomgarden ZT, Grunberger G, et al. American Association of Clinical Endocrinologists and American College of Endocrinology – Clinical Practice Guidelines for developing a diabetes mellitus comprehensive care plan. *Endocrine Practice*. 2015;21(suppl 1):1-87.
4. Grunberger G, Abelseth JM, Bailey TS, Bode BW, Handelsman Y, Hellman R, et al. Statement by the American Association of Clinical Endocrinologists (AACE)/American College of Endocrinology (ACE) consensus panel on insulin pump management. *Endocr Pract*. 2014;20(5):463-489.
5. American Diabetes Association. Standards of Medical Care in Diabetes—2017. *Diabetes Care* 2017;40(Suppl. 1).