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## External Insulin Pumps Corporate Medical Policy

File Name: External Insulin Pumps  
File Code: 1.01.VT30  
Origination: 04/2006  
Last Review: 04/2021  
Next Review: 04/2022  
Effective Date: 06/01/2021

### Description/Summary

An external insulin infusion pump is a programmable, battery-powered mechanical syringe/reservoir device controlled by a microcomputer to deliver a continuous subcutaneous insulin infusion (CSII) into the body. Typical devices have a two to three day supply of insulin connected to an infusion set attached to a small needle or cannula programmed to deliver a steady basal amount of insulin and release a bolus dose at meals and at programmed intervals. The purpose of the insulin pump is to provide an accurate, continuous, controlled delivery of insulin which can be regulated by the user to achieve intensive glucose control objectives and to prevent the metabolic complications of hypoglycemia, hyperglycemia and diabetic ketoacidosis. Other more recently developed devices are not battery powered and rely on mechanical instillation of programmed basal and bolus insulin. This document addresses the medically necessary uses of these devices.

### Policy

#### Coding Information

Click the links below for attachments, coding tables & instructions.

[Attachment I- HCPCS code table & instructions](#)

See the BCBSVT prior approval list for medical equipment to determine prior approval requirements for external insulin pumps.

#### When a service may be considered medically necessary

External insulin pumps may be considered **medically necessary** in the treatment of diabetic patients based on the following criteria.

All members must meet **ALL** of the general criteria:

- Completion of a diabetes self-management education program
- Treatment program including at least three insulin injections per day with frequent self-adjustments of insulin dose
- Documented frequent blood glucose self-testing 3-4 times per day prior to initiation of the insulin pump

Have been evaluated either by a pediatric endocrinologist or endocrinologist who feels that the member is capable of using a pump or hybrid closed loop system and that this treatment is in the best interests of the member.

External insulin pumps may be considered medically necessary for members who have and meet having a history of pancreatectomy (partial or complete/total) with **Devices/hybrid closed loop system with Low Glucose Suspend Feature.**

Use of a US Food and Drug Administration–approved automated insulin delivery system artificial pancreas device system designated as hybrid closed loop insulin delivery system (with low glucose suspend and suspend before low features) may be considered **medically necessary** in patients with type 1 diabetes who meet all of the following criteria:

- Age 2 and older
- Glycated Hemoglobin level lower than 10.0%
- Who meet all the general criteria listed above.

Supplies required for the proper use of a medically necessary external insulin pump, including custom-designed batteries and power supplies, are considered medically necessary. However, off-the-shelf batteries that can also be used to power non-medical equipment are considered convenience items and therefore a benefit exclusion.

### Enhanced Features

An external insulin pump with enhanced features may be considered **medically necessary** when the criteria for a standard external insulin pump are met and there is a documented special need, such as a vision\* or hearing impairment\*, that requires an additional or enhanced feature for successful use of an insulin pump.

\*legally blind or deaf

### Replacement of External Insulin Pump or System Component

The replacement of an existing external insulin pump, or an insulin pump system component required for the delivery of insulin, may be considered **medically necessary** for an individual with successfully managed type 1 or type 2 diabetes mellitus when BOTH of the following criteria are met:

1. The pump/component is malfunctioning; OR no longer under warranty; OR cannot be repaired

2. Health care provider managing the diabetes has seen the individual in the last six months and supports the need for a replacement device. When requesting a new pump due to a malfunction, documentation containing a complete description of the specific malfunction is required.

### Replacement of lost, stolen or destroyed Durable Medical Equipment

We will replace one lost, stolen or destroyed Durable Medical Equipment, prosthetic or orthotic per Plan Year if not covered by an alternative entity (including but not limited to homeowners insurance and automobile insurance) if:

- the Durable Medical Equipment, prosthetic or orthotic's absence would put the member at risk of death, disability or significant negative health consequences such as a hospital admission;
- the Durable Medical Equipment is still under warranty.

Note: In order to replace a stolen item we require you to submit documentation, such as a police report, with the request.

### Exclusions

We do not cover the replacement of a lost, stolen or destroyed Durable Medical Equipment, prosthetic or orthotic:

- if the criteria above have not been met; **AND**
- for more than one lost, stolen or destroyed Durable Medical Equipment, prosthetic or orthotic per Plan Year.

### When a service is considered investigational

Bihormonal, completely automated systems which use two commercially available pumps, one of which delivers insulin and the other glucagon are considered to be investigational

Do-it-yourself artificial pancreas systems (DIY APS) are not FDA approved and are considered to be investigational

### When a service is considered non-covered (benefit exclusion)

However, off-the-shelf batteries that can also be used to power non-medical equipment are considered convenience items and therefore a benefit exclusion.

Replacement of a functioning insulin pump, or additional software/hardware for the sole purpose of upgrading to the latest technology is considered a convenience and is therefore a benefit exclusion.

Deluxe features/items, add-ons, or upgrades that do not significantly enhance the functionality of the insulin pump or are for the ease of member/caregiver use is considered a convenience and is therefore a benefit exclusion.

Any treatment, Durable Medical Equipment, supplies or accessories intended principally

for participation in sports or recreational activities or for personal comfort or convenience.

When an external insulin pump does not provide a therapeutic benefit to a patient in need because of certain medical conditions or illnesses.

### Reference Resources

1. Blue Cross and Blue Shield Association Policy MPRM 1.01.30 Last Review June 2020.
2. BCBS Massachusetts medical Policy 332 Last updated 8/2018.

### Related Policies

Medical Equipment and Supplies (DME)  
Continuous or Intermittent Glucose Monitoring (CGMS) in Interstitial Fluid

### Document Precedence

Blue Cross and Blue Shield of Vermont (BCBSVT) Medical Policies are developed to provide clinical guidance and are based on research of current medical literature and review of common medical practices in the treatment and diagnosis of disease. The applicable group/individual contract and member certificate language, or employer's benefit plan if an ASO group, determines benefits that are in effect at the time of service. Since medical practices and knowledge are constantly evolving, BCBSVT reserves the right to review and revise its medical policies periodically. To the extent that there may be any conflict between medical policy and contract/employer benefit plan language, the member's contract/employer benefit plan language takes precedence.

### Audit Information

BCBSVT reserves the right to conduct audits on any provider and/or facility to ensure compliance with the guidelines stated in the medical policy. If an audit identifies instances of non-compliance with this medical policy, BCBSVT reserves the right to recoup all non-compliant payments.

## Administrative and Contractual Guidance

### Benefit Determination Guidance

Prior approval may be required and benefits are subject to all terms, limitations and conditions of the subscriber contract.

Incomplete authorization requests may result in a delay of decision pending submission of missing information. To be considered complete, see policy guidelines above.

NEHP/ABNE members may have different benefits for services listed in this policy. To confirm benefits, please contact the customer service department at the member's health plan.

Federal Employee Program (FEP): Members may have different benefits that apply. For further information please contact FEP customer service or refer to the FEP Service Benefit Plan Brochure. It is important to verify the member's benefits prior to providing the service to determine if benefits are available or if there is a specific exclusion in the member's benefit.

Coverage varies according to the member's group or individual contract. Not all groups are required to follow the Vermont legislative mandates. Member Contract language takes precedence over medical policy when there is a conflict.

If the member receives benefits through an Administrative Services Only (ASO) group, benefits may vary or not apply. To verify benefit information, please refer to the member's employer benefit plan documents or contact the customer service department. Language in the employer benefit plan documents takes precedence over medical policy when there is a conflict.

### Policy Implementation/Update information

|         |   |
|---------|---|
| 04/2006 | New Policy  |
| 04/2007 | Annual review. Medical necessity criteria updated and insulin pump with Real Time continuous glucose monitoring information added. Reviewed by CAC 05/2007.   |
| 07/2007 | Re-reviewed based on new controlled clinical trial information. Real time continuous glucose monitoring is considered investigational and not medically necessary.  |
| 02/2008 | Annual review. Individual consideration language and investigational definition updated and added on page 2. New BCBSA format used. Reviewed by CAC 03/2008.  |
| 11/2011 | Updated and placed in new format. Significant criteria revisions. ICD-10 coding added.  |
| 02/2014 | ICD-10 remediation. Updated standard language (document precedence, audit information added. Removed PA requirement for insulin pump supplies. RLJ.   |
| 08/2015 | Section headers added, updated and/or clarified. Other minor format changes. Approved in MPC on 8/31/15 RLG.  |
| 04/2017 | External input received with updates to medical criteria, removed fasting C-Peptide testing requirements. Reformatted medical criteria section to clarify language. Added "enhanced features section" ICD 10 table removed. |
| 10/2017 | Added language for History of pancreatectomy (partial or complete/total) under medical necessity criteria. Added lost/stolen durable medical equipment language.  |
| 11/2018 | Added BCBSA language for artificial pancreas.   |

|         |   |
|---------|---|
| 04/2019 | External Feedback received. Updated medical necessity criteria around Artificial Pancreas Devices/hybrid closed loop system with Low Glucose Suspend Feature, removed Investigational statements. Updated references. Updated coding table adding artificial pancreas devices.  |
| 01/2020 | Added codes A4226 & E0787 requiring prior approval if over DME dollar thresholds effective 01/01/2020.  |
| 06/2020 | Policy updated with changes under investigational section: added language around bihormonal completely automated systems and Do-it-yourself artificial pancreas systems. References updated. the policy statement to lower age cut off to 6 years of age.   |
| 04/2021 | External input received. Changed age criteria from 6 to 2 years and older as noted in policy statement -Use of a US Food and Drug Administration approved automated insulin delivery system artificial pancreas device system designated as hybrid closed loop insulin delivery system (with low glucose suspend and suspend before low features) may be considered medically necessary in patients with type 1 diabetes who meet all of the following criteria: Age 2 and older. |

**Eligible providers**

Qualified healthcare professionals practicing within the scope of their license(s).

**Approved by BCBSVT Medical Directors**

**Date Approved**

Joshua Plavin, MD, MPH, MBA  
Chief Medical Officer

Kate McIntosh, MD, MBA, FAAP  
Senior Medical Director

Attachment I  
HCPCS Code Table & Instructions

| Code Type  | Number | Description  | Policy Instructions                           |
|--|--------|--|---|
| <b>The following codes will be considered as medically necessary when applicable criteria have been met.</b> |        |  |   |
| HCPCS  | A4226  | Supplies for maintenance of insulin infusion pump with dosage rate | See DME prior approval list for requirements. |
| HCPCS  | E0784  | External ambulatory infusion pump, insulin                         | See DME prior approval list for requirements. |

|       |       |   |   |
|-------|-------|---|---|
| HCPCS | E0787 | External ambulatory infusion pump, insulin, dosage rate adjustment using therapeutic continuous glucose sensing   | See DME prior approval list for requirements. |
| HCPCS | S1034 | Artificial pancreas device system (e.g., low glucose suspend [LGS] feature) including continuous glucose monitor, blood glucose device, insulin pump and computer | See DME prior approval list for requirements. |
| HCPCS | S1035 | Sensor; invasive (e.g., subcutaneous), disposable, for use with artificial pancreas device system   | See DME prior approval list for requirements. |
| HCPCS | S1036 | Transmitter; external, for use with artificial pancreas device system   | See DME prior approval list for requirements. |
| HCPCS | S1037 | Receiver (monitor); external, for use with artificial pancreas device system  | See DME prior approval list for requirements. |
| HCPCS | S9145 | Insulin pump initiation, instruction in initial use of the pump (pump not included)   |   |