BlueCross BlueShield of Vermont

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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: 12/2024
Next Review: 12 /2025
Effective Date: 03/01/2025

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 members based on the following criteria.

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

- Completion of a diabetes self-management education program; **AND**
- Treatment program including at least three insulin injections per day with frequent self-adjustments of insulin dose; **AND**
- Documented frequent blood glucose self-testing, averaging at least three times per day prior to initiation of the insulin pump; **AND**
- Have been evaluated either by a pediatric endocrinologist or endocrinologist who supports that the member is capable of using a pump or hybrid closed loop system and that treatment is in the best interest of the member.

External insulin pumps may be considered **medically necessary** for members who have a history of pancreatectomy (partial or complete/total.)

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 members with type 1 diabetes who meet all of the following criteria:

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

Use of a US Food and Drug Administration cleared or approved automated insulin delivery system (artificial pancreas device system) designated as a closed-loop insulin delivery system may be considered **medically necessary** in members with type 1 diabetes who meet all of the following criteria:

- Age 6 years and older **AND** all of the following:
    - Clinical diagnosis of type 1 diabetes for 12 months or more;
    - Using insulin for at least 12 months;
    - Diabetes managed using the same regimen (either pump or multiple daily injections, with or without continuous glucose monitoring) for 3 months or longer.

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 a member with successfully managed type 1 or type 2 diabetes mellitus when BOTH of the following criteria are met:

1. The pump/component is malfunctioning and cannot be repaired **AND** is no longer under warranty
2. Healthcare provider is actively managing insulin pump therapy and provider documentation 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 **investigational**

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

considered **investigational.**

Use of an automated insulin delivery system (artificial pancreas device system) is **investigational** for members who do not meet the above criteria.

Use of an automated insulin delivery system (artificial pancreas device system) not cleared or approved by the FDA is **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 member in need because of certain medical conditions or illnesses.

Reference Resources

1. BlueCross BlueShield Association Medical Policy Reference Manual 1.01.30 – Artificial Pancreas Device Systems. Last reviewed: August 2024. Last accessed: November 2024.
2. BCBS Massachusetts Medical Policy 332 Last updated 8/2018.
3. UpToDate: Continuous subcutaneous insulin infusion (insulin pump). Literature review current through 10/2024. Accessed 11/2024.

Related Policies

Durable Medical Equipment
Prosthetics Orthotics and Supplies (DMEPOS)
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 compete, 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.

12/2022	Policy reviewed. Minor formatting changes. Clarified language for use following pancreatectomy. Clarification around replacement criteria. References and related policy sections updated.
11/2023	Policy reviewed and references updated. No changes to policy statement.
12/2024	Policy reviewed. New clinical criteria added for medically necessary use of closed-loop insulin delivery systems. Additional language around investigational use of artificial pancreas devices. References updated.

Eligible providers

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

Approved by BCBSVT Medical Directors

Tom Weigel, MD, MBA
Vice President and Chief Medical Officer

Tammaji P. Kulkarni, MD
Senior Medical Director

Attachment I
HCPCS Code Table & Instructions

Code Type	Number	Description	Policy Instructions
The following codes will be considered as medically necessary when applicable criteria have been met.			
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)	