



**MedStar Family
Choice**

DISTRICT OF COLUMBIA

ADMINISTRATIVE POLICY AND PROCEDURE

Policy #:	1413.DC	
Subject:	External Insulin Pumps	
Section:	Medical Non-Pharmacy Protocols	
Initial Effective Date:	10/01/2020	
Revision Effective Date(s):	07/21, 07/22, 07/23, 07/24, 07/25	
Review Effective Date(s):		
Responsible Parties:	Medical Director Health Plan Pharmacist Manager, Utilization Management	
Responsible Department(s):	Clinical Operations	
Regulatory References:	N/A	
Approved:	Director, Clinical Operations	Senior Medical Director (Chief Medical Officer-DC)

Purpose: It is the purpose of this policy to define the criteria and limitations established for the use of External Insulin Pumps in Enrollees with Type 1 and Type 2 Diabetes.

Scope: MedStar Family Choice District of Columbia

Policy: It is the policy of MedStar Family Choice DC to authorize External Insulin Pumps when it is medically necessary as outlined in the criteria below. Requests that do not specifically meet the criteria may be submitted with supporting medical records, articles from the literature, etc. and will be reviewed by a Medical Director or Health Plan Pharmacist for a medical exception.

Procedure:

A. Medical Description/Background:

- External Insulin pumps offer an alternative delivery method for subcutaneous insulin for the treatment of diabetes mellitus Type 1 and Type 2. The American Association of Clinical Endocrinologist (AACE) issued guidelines in 2021 regarding the use of advanced technology in the management of persons with diabetes including continuous subcutaneous insulin infusion (CSII). In 2025 the American Diabetes Association (ADA) updated Diabetes Technology: Standards of Care. Pump therapy requires appropriate

patient selection, which is a critical factor for success. A thorough assessment of the patient's diabetes knowledge and management principles is recommended. Prospective pump users or caregivers must understand pump usage and must be able to troubleshoot pump complications (i.e., infusion set or pump failure). Regardless of the insulin pump system patients must be able to count carbohydrates and monitor blood glucose levels frequently or verify blood glucose level if the continuous glucose monitor (CGM) reading does not match symptoms.

2. Sensor-augmented insulin pump therapy can also suspend basal insulin delivery either in response to a low sensor glucose value or when the CGM predicts hypoglycemia.
3. Automated delivery insulin pumps can be used alone or in conjunction with a CGM device which can automatically adjust basal rate delivery (increase or decrease) in response to CGM readings. The newer insulin pumps/CGM systems when placed in the "auto" mode is referred to Hybrid closed-loop insulin pumps, with the capacity to both increase or reduce basal insulin deliver based on sensor glucose values. Both systems will still require the user to bolus for carbohydrate intake and correctional doses.
4. An alternative option is a disposable patch pump. The patch pump is a tubeless device. Two examples are the Omnipod and the V-GO. The Omnipod is attached to the skin and controlled by a hand-held device or personal diabetes manager (PDM). It provides non-stop insulin delivery for up to 3 days (72 hours) and is waterproof. The V-GO is a simple all-in-one basal-bolus insulin delivery option designed for patients with type 2 diabetes that is worn like a patch. V-Go uses only U-100 fast acting insulin and is filled using the EZ Fill accessory. It delivers insulin at a preset basal rate and on demand bolus dosing.

B. Indications for Insulin Pump Therapy:

1. Enrollees must meet all the following criteria:
 - a. Insulin pumps must be ordered and managed by an endocrinologist and/or diabetes specialist.
 - b. The patient or their parent/caregiver must have completed a diabetes self-management education program within the past year and is able to count carbohydrates.
 - c. The patient must require multiple daily injections (at least three insulin injections per day) for at least 6 months prior to initiation of insulin pump OR has type 1 diabetes
 - d. The patient must test blood glucose levels at least 3 times per day during the 60 days prior to the request for an insulin pump or be compliant with using a CGM device ($\geq 70\%$ utilization during lookback period).
 - e. The patient must possess the ability to understand insulin pump technology and is able to take action based on glucose data interpretation.

Insulin pump must be FDA approved for the Enrollee's condition and age.

C. Information Required for External Insulin Pump Review: The insulin pump company should fax a request for authorization with supporting documentation to MedStar Family Choice. Authorization requests for insulin pumps are not taken via phone.

1. Order/prescription/request for pre-authorization must include the following:
 - a. Diagnosis Code
 - b. Type of insulin pump
 - c. HCPC codes, description and quantities for insulin pump and supplies

2. Clinical documentation to support medical necessities including the following:
 - a. A Certificate of Medical Necessity (CMN) signed by the prescribing provider (endocrinologist or physician/nurse practitioner specializing in diabetes). This must include the following:
 - i. Frequency of blood glucose self-testing, blood glucose range, recent hemoglobin A1C.
 - ii. Frequency recommended for changing of infusion sets/pods.
 - iii. Diagnosis Code.
 - iv. Diabetes Complications.
 - b. Office visit notes from the last two encounters with the prescribing provider. The prescriber's note should support the information in the Certificate of Medical Necessity.
 - c. Documented blood glucose self-testing 3 times per day in the 60 days prior to the pump request (or being monitored by CGM). A blood glucose log downloaded by the prescribing provider from an Enrollee's blood glucose meter is preferred.
 - d. Documentation of recent diabetes education.

D. Continued Coverage of An External Insulin Pump and Supplies:

1. Enrollees require follow-up care and evaluation by an endocrinologist or practitioner specializing in diabetes at least every six months or more frequently if specified by the prescribing practitioner.
2. Supplies are considered medically necessary and are provided through MFC DME supplier with the exception for disposable insulin delivery systems (see F).

E. Limitations/Exclusions:

1. Implantable insulin pumps are not a covered benefit.
2. Devices under warranty are not a covered benefit and are the liability of the manufacturer.
 - a. Replacement of insulin pumps under warranty is not a covered benefit.
Note: Typical pump warranty is 4 years.
3. Insulin Pumps that are not FDA approved for the Enrollee's condition and age will not be considered.

F. disposable insulin delivery system

1. Background:

There are several disposable insulin systems on the market currently; Omnipod is one of them

Omnipod is made of two main components: the Pod and a smartphone-like Controller. The pod receives insulin delivery instructions from the Controller and then delivers insulin into the body through a small, flexible tube called a cannula. It

also has a version which automatically increases, decreases, or pauses insulin every 5 minutes, based on a customized target..

2. Limitations for Disposable insulin delivery systems:
It is a pharmacy benefit and not processed as DME.

References

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5. U.S Food and Drug Administration (FDA). FDA News Release: FDA approves first-of-its-kind automated insulin delivery and monitoring system for use in young pediatric patients. Available at: <https://www.fda.gov/news-events/press-announcements/fda-approves-first-its-kind-automated-insulin-delivery-and-monitoring-system-use-young-pediatric>. Accessed 04/17/2025
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8. [What is Omnipod? | Tubeless Insulin Pump Therapy](#)
Accessed 04/17/2025

Summary of Changes:	07/25: <ul style="list-style-type: none">• Updated Director, Clinical Operations
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	<ul style="list-style-type: none"> • Updated reference date for American Diabetes Association. Standards of Medical Care in Diabetes. • Updated References • Broadened eligibility for coverage criteria • Simplified Disposable insulin delivery systems section reflecting coverage through pharmacy benefits <p>07/24:</p> <ul style="list-style-type: none"> • Updated Responsible Parties to include only position titles and not names. <p>07/23:</p> <ul style="list-style-type: none"> • Removed 2022 ADA standards, AACE/ACE2014 consensus statement and AACE 2010 statement on Insulin Pumps from regulatory references. • Added Health Plan Pharmacist Manager, Utilization Management to responsible parties. • Added Health Plan Pharmacist as possible reviewer. • Updated Medical decision/Background section A. • Updated Indications for Insulin Pump Therapy section B. • Deleted references to brand names of Insulin Pumps and clarified “FDA approved” meaning in Limitations/Exclusions section. <p>07/22:</p> <ul style="list-style-type: none"> • Updated Responsible Parties. • Updated Approved Updated American Diabetes Association. Standards of Medical Care in Diabetes date in References section. <p>07/21:</p> <ul style="list-style-type: none"> • Updated Responsible Parties. • Update Regulatory References. • Updated Background section. • Updated Limitations and exclusions section. • Updated References. <p>10/20:</p> <ul style="list-style-type: none"> • New policy.
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