MedStar Family Choice

ADMINISTRATIVE POLICY AND PROCEDURE		
Policy #:	**1413**	
Subject:	**External Insulin Pumps**	
Section:	**Medical Non-Pharmacy Protocols**	
Initial Effective Date:	**12/01/2015**	
Revision Effective Date(s):	**07/18, 07/19, 07/20, 07/21, 10/21, 07/22,07/23, 07/24**	
Historical Revision Date(s):	**10/16, 07/17**	
Review Effective Date(s):		
Historical Review Date(s):	**06/16**	
Responsible Parties:	**M**edical Director, Manager of Utilization Management	
Responsible Department(s):	**Clinical Operations**	
Regulatory References:	**N/A; see references below**	
Approved:	AVP of Clinical Operations,	**Chief Medical Officer**

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

Scope: **MedStar Family Choice, Maryland**

Policy: **It is the policy of MedStar Family Choice 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 for a medical exception.**

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 2024 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 (ie. 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.

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.

Automated insulin delivery systems consist of insulin pumps , a CGM device and an algorithm which can automatically adjust basal rate delivery (increase or decrease) in response to CGM readings. The systems when placed in the "auto" mode are referred to Hybrid closed-loop mode, with the capacity to both increase or reduce basal insulin delivery based on sensor glucose values. The currently used systems will still require the user to manually enter carbohydrate intake to calculate prandial boluses as well as adjustments for physical activity.

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 a tubeless insulin pump system with 2 components: a pod filled with insulin 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 waterproof1. It also has a version which automatically increases, decreases, or pauses insulin every 5 minutes, based on the customized target. 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. Members must meet all the following criteria:
      a. Insulin pumps must be ordered and managed by an endocrinologist and/or diabetes specialist.
      b. The patient 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.
      d. The patient must test blood glucose levels at least 4 times per day during the 60 days prior to the request for an insulin pump or on a CGM.
      e. The patient must possess the ability to understand insulin pump technology and is able to act based on glucose data interpretation.
      f. The patient meets at least one of the supporting criteria for medical necessity:
         i. Evidence of "inadequate glycemic control" as evidenced by HbA1c greater than a set target (A1c >7%), episodes of persistent hyperglycemia

(>180mg/dl) or diabetic ketoacidosis despite compliance with adjustments in self-monitoring and insulin administration regimens.
ii. Frequent and unpredictable wide fluctuations in blood glucose levels despite insulin adjustments.
iii. Documented recurring episodes of severe unexplained hypoglycemia (<54mg/dl) and/or hypoglycemia unawareness).
iv. People with type 1 diabetes

2. Insulin pump must be FDA approved for member'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 necessity 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 4 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 a member's blood glucose meter is preferred.
      d. Documentation of recent diabetes education.

D. Continued Coverage of an External Insulin Pump and Supplies:
   1. Members 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 **MedStar Family Choice** 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 member's condition and age will not be considered.

F. Disposable insulin delivery systems (V-GO, Omnipod)

1. Background:
   a. The V-GO Insulin Delivery device is a simple all-in-one basal-bolus insulin delivery option designed for patients with type 2 diabetes that is worn like a patch. It can eliminate the need for taking multiple daily shots, simplify insulin regimen and increase adherence. It delivers a continuous preset basal rate of insulin over 24 hours and provides discreet on-demand bolus dosing in 2-unit increments at mealtimes with a click of a button.
   b. 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. Unlike V-Go Omnipod 5 is indicated for type 1 diabetes and Omnipod Dash is suitable for the patients with both Type 2 and Type 1 diabetes.
2. Disposable insulin delivery system will be evaluated on a case-by-case basis. Submitted clinical documentation will be reviewed for appropriateness of device and/or need for redirection.
3. Information Required for Disposable insulin delivery systems review:
   a. Authorization Request (can use the Pharmacy Authorizations Form available at www.medstarfamilychoice.com).
   b. Office visit notes from the last two encounters with the prescribing provider to support Medical Necessity.
   c. History of diabetes and any diabetes complications.
   d. Documentation of uncontrolled diabetes on multiply daily insulin injections.
   e. Prescribed by an Endocrinologist or practitioner who specializes in diabetes with evidence of a face-to-face visit within the past 3 months or less if specified by the prescribing .practitioner
   f. Members have the ability to understand and safely use the device.
   g. Documentation that member has been educated on device.
   h. Documentation of self-blood glucose monitoring (30-day blood glucose log) and/or reasons for not testing.

4. Limitations for Disposable insulin delivery systems:
   a. Patients who make regular adjustments or modifications to their basal rate during a 24-hour period, or whose amount of insulin used at meals requires adjustments of less the 2-Unit increments should not use V-GO as it may result in hypoglycemia.
   b. It is a pharmacy benefit and not processed as DME.

References

1. American Diabetes Association. Standards of Medical Care in Diabetes-2024. Diabetes Care 2024;47(Suppl.1). https://diabetesjournals.org/care/article/47/Supplement_1/S126/153939/7-Diabetes-Technology-Standards-of-Care- in
2. The American Association of Clinical Endocrinologists. (2021, June). George Grunberger MD, FACP, MACE, Co-Chair et al. American Association of Clinical Endocrinologists Clinical Practice Guideline: The Use of Advanced Technology in the management of Persons With Diabetes Mellitus. *In Endocrine Practice*. (Volume 27, Issue 6, June 2021, Pages 505-537)Retrieved 05/12/2023 https://doi.org/10.1016/j.eprac.2021.04.008
3. VGO Wearable Insulin Delivery. Available at: https://www.go-vgo.com/hcp/. Accessed 05/09/2023
4. U.S Food and Drug Administration (FDA). FDA News Release: FDA authorizes first interoperable, automated insulin dosing controller designed to allow more choices for patients looking to customize their individual diabetes management device. Available at: https://www.fda.gov/news-events/press-announcements/fda-authorizes-first-interoperable-automated-insulin-dosing-controller-designed-allow-more-choices Accessed 5/18/2024
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 05/18/2024
6. Safety of a Hybrid Closed-Loop Insulin Delivery System in Patients with Type 1 Diabetes. Bergenstal RM, Garg S, Weinzimer SA, Buckingham BA, Bode BW, Tamborlane WV, Kaufman FR. JAMA. 2016 Oct;316(13):1407-1408.
7. . Omnipod® 5 Automated Insulin Delivery System | Omnipod
8. What is Omnipod? | Tubeless Insulin Pump Therapy

Summary of Changes:	**0**7/24 • Removed specific names from "responsible parties" and changed to titles- Medical Director and Manager of Utilization Management • Removed specific names from "approved" and changed to titles AVP of Clinical Operations and Chief Medical Officer • Updated reference date for American Diabetes Association. Standards of Medical Care in Diabetes. • Clarified description of automated insulin delivery systems • Clarified description of disposable patch pumps

	• **D**eleted DM case management assessment from indications criteria. • **C**larified Information Required for External Insulin Pump Review • **A**dded Omnipod to Disposable insulin delivery systems and References. **07/23:** • **R**emoved 2022 ADA standards, AACE/ACE2014 consensus statement and AACE 2010 statement on Insulin Pumps from regulatory references; added Maryland ECRO standard • Updated approved by to Carol Attia and Dr. Wills • 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 **07/22:** • Updated responsible parties from Dr. Toye, Theresa Bittle and Nitza Larbie to Dr. Kats, Blaine Willis and Teresa Boileau. • Updated American Diabetes Association. Standards of Medical Care in Diabetes date in References section. • Formatted reference section. **10/21:** • Section B item d.- added "or on a CGM" to acknowledge the increasing use of this technology. **07/21:** • Removed Sharon Henry from Responsible Parties. • Updated Responsible Departments from Utilization management to Clinical Operations. • Added "Maryland" to scope. • Updated Background section. • Updated Limitations and exclusions section. • Updated References. **07/20:** • Updated Section from Care Management to Medical Non-Pharmacy Protocols. • Clarified insulin pump patient selection. • Added FDA age limits for The Tandem T:slim with Control-IQ

	• Updated references and links. **07/19:** • Removal of "Maryland" from scope. • Changed Priscilla Thomas to Nitza Larbie in "Responsible Parties." • Added VGO review requirements. • Added and deleted references. • Updated Limitations and Exclusions. • Removed Acceptable Variations of External Insulin Infusion Pumps. **07/18:** • Removed references to DC health plans. • Updated references. • Modified Effective Date to Initial Effective Dates; added Historical Revision Dates and Revision Effective Dates; and added Historical Review Dates and Review Effective Dates. **07/17:** • Added Responsible Parties. • Changed "Physician Advisor" to "Medical Director." • Changed Carol Attia to Theresa Bittle and updated Dr. Patryce Toye's title from Senior Medical Director to Chief Medical Officer. • 2017 ADA Guideline utilized. **10/16:** • Under #2: Deleted reference to (e.g., MiniMed Paradigm VEO and MiniMed 530G with Enlite Sensor; and Animas VIBE). **06/16:** • No changes. **12/15:** • New Policy.