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**	
Review Effective Date(s):		
Responsible Parties:	**Medical Director** **Health Plan Pharmacist** **Manager, Utilization Management**	
Responsible Department(s):	**Clinical Operations**	
Regulatory References:		
Approved:	**Sharon Henry, RN** **Director, Clinical Operations**	**Raymond Tu, MD** **Sr. Medical Director (CMO)**

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 (MFC-DC)**

Policy: **It is the policy of MFC-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:
   1. 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 2023 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 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). 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.

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.
      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 be compliant with using a CGM device (≥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.
      f. DM Case Management will assess individual's readiness and understanding of insulin pump use and will assess and review diabetes education for optimal pump safety and success.
      g. 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).Type 1 diabetes diagnosis

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 (MFC) Fax 410-933-2274. 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. Perthes 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. 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.
   2. Supplies are considered medically necessary and are provided through MFC DME supplier.

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. Nonprogrammable disposable insulin delivery system (V-GO)

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 at mealtimes with a click of a button.
2. Nonprogrammable 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.

G. Information Required for V-GO review:
1. Authorization Request (can use the Pharmacy Authorizations Form available at www.medstarfamilychoice.com).
2. Office visit notes from the last two encounters with the prescribing provider to support Medical Necessity.
3. History of type 2 diabetes and any diabetes complications.
4. Documentation of uncontrolled diabetes on multiply daily insulin injections.
5. Prescribed by an Endocrinologist or practitioner who specializes in diabetes with evidence of a face-to-face visit within the past 3 months.
6. Enrollee has the ability to understand and willingness to use the device.
7. Documentation that Enrollee has been educated on device.
8. Documentation of self-blood glucose monitoring (60-day blood glucose log) and/or reasons for not testing. Not approved for convenience.

H. Limitations for V-GO:
1. 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.
2. It is a pharmacy benefit and not processed as DME.

References

1. American Diabetes Association. Standards of Medical Care in Diabetes-2023. Diabetes Care 2023;46(Suppl.1). https://professional.diabetes.org/content-page/practice-guidelines-resources
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 Mellitius. *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 5/9/2023
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 05/13/2023
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.

Summary of Changes:	**07/23:** • 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. **07/22:** • Updated Responsible Parties. • Updated Approved Updated American Diabetes Association. Standards of Medical Care in Diabetes date in References section. **07/21:** • Updated Responsible Parties. • Update Regulatory References. • Updated Background section. • Updated Limitations and exclusions section. • Updated References. **10/20:** • New policy.