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**	
Historical Revision Date(s):	**10/16, 07/17**	
Review Effective Date(s):		
Historical Review Date(s):	**06/16**	
Responsible Parties:	**Inna Kats, MD, Blaine Willis, and Teresa Boileau**	
Responsible Department(s):	**Clinical Operations**	
Regulatory References:	**2022 ADA Standards of Medical Care in Diabetes** **AACE/ACE 2014 Consensus Statement on Insulin Pump Management Task Force** **AACE 2010 Statement on Insulin Pump Management Endocr. Pract. 2010; 16 (No. 5)**	
Approved:	**Theresa Bittle, RN** **AVP, Clinical Operations**	**Patryce A. Toye, MD** **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 MFC 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) released a statement in 2010 regarding continuous subcutaneous insulin infusion (CSII). 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. According to AACE (2010), "Patients must be motivated and willing to work with providers to succeed using this complex therapy."

Automated delivery insulin pumps can be used alone or in conjunction with a CGM device which can automatically adjust basal rate delivery in response to CGM readings. This is known as sensor-augmented insulin pump therapy that can also suspend basal insulin delivery either in response to a low sensor glucose value or when the CGM predicts hypoglycemia. 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.

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. 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 four 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. 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).

C. Information Required for External Insulin Pump Review: The insulin pump company (ie. Medtronic, Tandem or Insulet) 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 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. 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.
   2. Supplies are considered medically necessary and are provided through MFC DME supplier.

E. Limitations/Exclusions:
   1. The Omnipod Dash insulin pump is a pharmacy benefit and not processed as DME.
   2. The MiniMed 670G hybrid closed-loop system with Smart Guard technology is FDA approved for children with T1DM aged 7 and older.
   3. The MiniMed 770G hybrid closed-loop system with Smart Guard technology is FDA approved for children with T1DM age 2 and older.
   4. The Tandem T: slim with Basal-IQ is FDA approved for children age 6 and older.
   5. The Tandem T: slim with Control-IQ is FDA approved for management of type 1 diabetes in persons 14 years of age and older.

6. Implantable insulin pumps are not a covered benefit.
7. 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.
8. Insulin Pumps that are not FDA approved 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.
3. Information Required for V-GO 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 type 2 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.
    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 V-GO:
    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

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4. VGO Wearable Insulin Delivery. Available at: https://www.go-vgo.com/hcp/. Accessed 4/6/2022.
5. 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 5/6/20
6. 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: www.fda.gov/news-events/press-announcements/fda-approves-first-its-kind-automated-insulin-delivery-and-monitoring-system-use-young-pediatric. Accessed 5/5/21
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8. Bergenstal RM, Garg S, Weinzimer SA, Buckingham BA, Bode BW, Tamborlane WV, Kaufman FR. JAMA. 2016 Oct;316(13):1407-1408.

Summary of Changes:	**07/22:** • 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.