



**ADMINISTRATIVE POLICY AND PROCEDURE**

<b>Policy #:</b>	<b>1413</b>	
<b>Subject:</b>	<b>External Insulin Pumps</b>	
<b>Section:</b>	<b>Medical Non-Pharmacy Protocols</b>	
<b>Initial Effective Date:</b>	<b>12/01/2015</b>	
<b>Revision Effective Date(s):</b>	<b>07/18, 07/19, 07/20</b>	
<b>Historical Revision Date(s):</b>	<b>10/16, 07/17</b>	
<b>Review Effective Date(s):</b>		
<b>Historical Review Date(s):</b>	<b>06/16</b>	
<b>Responsible Parties:</b>	<b>Patryce Toye, MD, Theresa Bittle, Nitza Larbie, and Sharon Henry</b>	
<b>Responsible Department(s):</b>	<b>Utilization Management</b>	
<b>Regulatory References:</b>	<b>2020 ADA Standards of Medical Care in Diabetes AAACE/ACE 2014 Consensus Statement on Insulin Pump Management Task Force AAACE 2010 Statement on Insulin Pump Management Endocr. Pract. 2010; 16 (No. 5)</b>	
<b>Approved:</b>	<b>Theresa Bittle, RN AVP, Clinical Operations</b>	<b>Patryce A. Toye, MD Chief Medical Officer</b>

**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

**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. Insulin pumps consist of a reservoir, a pump, and an infusion set or pod. The reservoir typically contains a two to three day supply of insulin which is delivered by a battery powered pump. The infusion set is comprised of

tubing which allows delivery of insulin from the reservoir to a subcutaneously placed cannula or a tubeless device attached to the skin controlled by a hand-held device, as in the case of the Omnipod insulin pump. The cannula can be inserted in the abdomen, upper thigh, lower back or upper arm. Insulin pumps require the infusion set and reservoir or pod to be changed every two to three days (Reece & Wilson, 2014). Insulin pumps can deliver rapid acting insulin 24 hours a day. This consists of basal rates, bolus doses to cover meals and correction/supplemental doses.

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 problems. The hybrid closed-loop insulin pumps communicate with a continuous glucose monitor (CGM). Regardless of insulin pump system patients must be able to count carbohydrates and monitor blood glucose levels frequently or verify blood glucose level if 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."

Pump therapy can also be utilized for persons with type 2 diabetes who require insulin, particularly in large amounts. These patients typically incur severe insulin resistance and poor glycemic control. It has been noted that pump therapy will reduce both insulin requirements and decrease A1C levels in these patients (Reece & Wilson, 2014).

## 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 of insulin (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.
  - 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).

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 410-933-2205. 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. Insulin pumps are not approved for convenience.
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 Tandem T: slim with Basal-IQ is FDA approved for children age 6 and older.

4. The Tandem T:slim with Control-IQ is FDA approved for management of type 1 diabetes in persons 14 years of age and older.
  5. Implantable insulin pumps are not a covered benefit.
  6. 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.
  7. 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.
- G. Information Required for VGO review:
1. Authorization Request (can use the Pharmacy Authorizations Form available at [www.medstarfamilychoice.com](http://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. Member has the ability to understand and willingness to use the device.
  7. Documentation that member 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 VGO:

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**

American Diabetes Association. Standards of Medical Care in Diabetes-2019. *Diabetes Care* 2020;43(Suppl. 1): S77-S88.

The American Association of Clinical Endocrinologists. (2010, September/October). Statement by the American Association of Clinical Endocrinologists Consensus Panel on Insulin Pump Management. In *Endocrine Practice*. Retrieved December 2, 2015.

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VGO Wearable Insulin Delivery. Available at: <https://www.go-vgo.com/hcp/>. Accessed 6/1/2020.

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

New Closed-Loop Pump Options. Available at: <https://uscdiabetes.com/closedloop.html>. Accessed 5/6/20

<b>Summary of Changes:</b>	<b>07/20:</b> <ul style="list-style-type: none"><li>• Updated Section from Care Management to Medical Non-Pharmacy Protocols.</li><li>• Clarified insulin pump patient selection.</li><li>• Added FDA age limits for The Tandem T:slim with Control-IQ</li><li>• Updated references and links.</li></ul> <b>07/19:</b>
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	<ul style="list-style-type: none"> <li>• Removal of “Maryland” from scope.</li> <li>• Changed Priscilla Thomas to Nitza Larbie in “Responsible Parties.”</li> <li>• Added VGO review requirements.</li> <li>• Added and deleted references.</li> <li>• Updated Limitations and Exclusions.</li> <li>• Removed Acceptable Variations of External Insulin Infusion Pumps.</li> </ul> <p><b>07/18:</b></p> <ul style="list-style-type: none"> <li>• Removed references to DC health plans.</li> <li>• Updated references.</li> <li>• Modified Effective Date to Initial Effective Dates; added Historical Revision Dates and Revision Effective Dates; and added Historical Review Dates and Review Effective Dates.</li> </ul> <p><b>07/17:</b></p> <ul style="list-style-type: none"> <li>• Added Responsible Parties.</li> <li>• Changed “Physician Advisor” to “Medical Director.”</li> <li>• Changed Carol Attia to Theresa Bittle and updated Dr. Patryce Toye’s title from Senior Medical Director to Chief Medical Officer.</li> <li>• 2017 ADA Guideline utilized.</li> </ul> <p><b>10/16:</b></p> <ul style="list-style-type: none"> <li>• Under #2: Deleted reference to (e.g., MiniMed Paradigm VEO and MiniMed 530G with Enlite Sensor; and Animas VIBE).</li> </ul> <p><b>06/16:</b></p> <ul style="list-style-type: none"> <li>• No changes.</li> </ul> <p><b>12/15:</b></p> <ul style="list-style-type: none"> <li>• New Policy.</li> </ul>
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