MedStar Family Choice		
ADMINISTRATIVE POLICY AND PROCEDURE		
Policy #:	**1413**	
Subject:	**External Insulin Pumps**	
Section:	**Care Management**	
Initial Effective Date:	**12/01/2015**	
Revision Effective Date(s):	**07/18**	
Historical Revision Date(s):	**10/16, 07/17**	
Review Effective Date(s):		
Historical Review Date(s):	**06/16**	
Responsible Parties:	**Patryce Toye, MD, Theresa Bittle, Priscilla Thomas, and Sharon Henry**	
Responsible Department(s):	**Utilization Management**	
Regulatory References:	**2018 ADA Standards of Medical Care in Diabetes** **AACE 2010 Statement on Insulin Pump Management** **AACE/ACE 2014 Consensus Statement on insulin pump management task force**	
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, MD**

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. 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 or short 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. They must also be able to count carbohydrates and monitor blood glucose levels frequently (preferably 6-8 times per day, but at least 4 times per day). 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 of 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.
        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. Acceptable Variations of External Insulin Infusion Pumps:
1. A programmable disposable external insulin infusion pump (e.g. OmniPod Insulin Management System) is an acceptable alternative to a standard insulin infusion pump for persons who meet medical necessity criteria. It is a wireless system.

2. Standard pump therapy (pump only).

3. Sensor augmented pump therapy - Integrated Insulin pump therapy with real time continuous glucose monitoring known as sensor augmented pump (SAP) therapy represents an important advancement in diabetes technology. These pumps are defined by their ability to incorporate real time glucose values to an active insulin pump via radio frequency (Tumminia et al., 2015). SAP therapy may include a low glucose suspend feature that will automatically suspend basal insulin delivery for up to 2 hours in response to real-time low blood glucose reading. This platform can improve metabolic control, reduce hypoglycemia/nocturnal hypoglycemia, decrease HbA1C and reduce glycemic variability.

   The SAP therapy should be utilized by those with Type 1 diabetes with a history of severe hypoglycemia, hypoglycemia unawareness and elevated HbA1C. According to recent case studies, successful utilization of SAP therapy is fostered by patient motivation and diabetes education/training on technical devices (Tumminia et al., 2015). This includes a history of appropriate self-management skills and collaboration with a diabetes specialist to enhance and incorporate strategies to improve patient outcomes.

   Positive outcomes are based on CGM adherence. According to the Sensor Augmented Pump Therapy for A1C Reduction study, wearing the CGM at least 60 – 70% of the time predicted significant HbA1C reduction (Tumminia et al., 2015). SAP therapy works best when used appropriately and consistently. Other success factors would include correct interpretation of real time CGM receiver trend arrows and awareness of the lag-time period.

D. Limitations/Exclusions:
1. Insulin pumps are not approved for convenience.

2. Implantable insulin pumps are not a covered benefit.

3. Nonprogrammable disposable insulin delivery systems will be evaluated on a case-by-case basis.

4. Approval for a new insulin pump:
    a. The replacement of insulin pumps that are out of warranty, are malfunctioning, and/or cannot be refurbished may be considered medically necessary. Appropriate clinical documentation will be required.
        i. Replacement insulin pumps with an integrated continuous glucose monitor require clinical documentation including a blood glucose log to support medical necessity.
    b. Replacement of a functioning insulin pump with an insulin pump with a continuous glucose monitor is not considered to be medically necessary.
    c. Replacement of insulin pumps under warranty is not a covered benefit unless considered medically necessary (e.g., child needing larger reservoir). Note: Typical pump warranty is 4 years.

5. Insulin Pumps that are not FDA approved will not be considered.

E. 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) Maryland at 410-933-2205 Attention Diabetes Disease Manager (DDM). 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 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 and make note of the type of blood glucose monitor the patient is currently using**.**
        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.

F. 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.

References

American Diabetes Association. Standards of Medical Care in Diabetes-2018. Diabetes Care 2018;41(Suppl. 1):S4-S141.

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Reece, S. W., & Williams, C. H. (2014). Insulin pump class: Back to the basics. In *Diabetes Spectrum*. Retrieved December 16, 2015, from http://spectrum.diabetesjournals.org/content/27/2/135.full.pdf+html. Tumminia, A., Sciacca, L., Frittitta, L., Squatrito, S., Vigneri, R., Le Moli, R., & Tomasell, L. (2015, May 14).

Integrated insulin pump therapy with continuous glucose monitoring for improved adherence: technology update. In *Dovepress*. Retrieved December 16, 2015, from https://www.dovepress.com/integrated-insulin-pump-therapy-with-continuous-glucose-monitoring-for-peer-reviewed-article-PPA

Summary of Changes:	**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.