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Clinical UM Guideline

Subject:	**External Insulin Pumps**		
Guideline #:	**CG-DME-51**	**Publish Date:**	**01/03/2024**
Status:	**New**	**Last Review Date:**	**11/09/2023**

Description

This document addresses the use of external insulin pumps, which provide subcutaneous insulin infusion to treat diabetes mellitus.

Note: Some external insulin pump devices come equipped with the capacity to be combined with continuous interstitial glucose monitor (CGM) devices to create automated insulin delivery systems. Devices with such features may be used as stand-alone insulin pumps or as combined systems, depending upon an individual's need.

Note: For additional information regarding diabetes care, please see:

- **CG-DME-42 Continuous Glucose Monitoring Devices**
- **CG-DME-50 Automated Insulin Delivery Systems**
- **CG-SURG-79 Implantable Infusion Pumps**

Clinical Indications

Medically Necessary:

External insulin pumps (either disposable or durable) are considered medically necessary when the following criteria are met:

A. The individual has documented diabetes mellitus (any type); and
B. The individual or caregiver(s) has completed a comprehensive diabetes education program; and
C. Both of the following criteria are met:
  1. **Insulin injections are required multiple times daily; and**
  2. **Multiple blood glucose tests are required daily or a continuous glucose monitor is being used.**

***Refills* for medically necessary disposable external insulin pumps are considered medically necessary.**

***Continued use* of an external insulin pump (including for individuals who used a continuous insulin infusion pump prior to enrollment with this plan) is considered medically necessary when the device has resulted in clinical benefit (for example, improved or stabilized HbA1c control or fewer episodes of symptomatic hypoglycemia or hyperglycemia).**

Replacement pumps:

The *replacement* of external insulin pumps is considered medically necessary when the following criteria have been met:

A. The device is out of warranty; and
B. The device is malfunctioning; and
C. The device cannot be refurbished.

Note: The medical necessity of the replacement of an external insulin pump for pediatric individuals (under 18 years of age) who require a larger insulin reservoir will be considered on a case-by-case basis. The following information is required when submitting requests:
A. Current insulin pump reservoir volume; and
B. Current insulin needs; and
C. Current insulin change out frequency required to meet individual needs.

Not Medically Necessary:

The use of an external insulin pump is considered not medically necessary when the criteria above have not been met.

***Continued use* of an external insulin pump is considered not medically necessary when continued use criteria above have not been met.**

***Replacement* of currently functional and warranted external insulin pumps is considered not medically necessary when the criteria above have not been met, including when the request is to upgrade to a newer pump with additional features.**

Coding

The following codes for treatments and procedures applicable to this guideline are included below for informational purposes. Inclusion or exclusion of a procedure, diagnosis or device code(s) does not constitute or imply member coverage or provider reimbursement policy. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage of these services as it applies to an individual member.

When services may be Medically Necessary when criteria are met:
For the following codes or when the code describes an external insulin pump:

HCPCS	
A9274	External ambulatory insulin delivery system, disposable, each, includes all supplies and accessories
E0784	External ambulatory infusion pump, insulin [when specified as a stand-alone insulin pump]

ICD-10 Diagnosis	
E08.00-E13.9	Diabetes mellitus
O24.011-O24.93	Diabetes mellitus in pregnancy, childbirth and the puerperium
P70.2	Neonatal diabetes mellitus

When services are Not Medically Necessary:

For the procedure codes listed above when criteria are not met or for all other diagnoses not listed; or when the code describes a procedure, device or situation designated in the Clinical Indications section as not medically necessary.

Discussion/General Information

Diabetes is one of the most common chronic diseases in the United States (U.S.), with approximately 37 million Americans with diagnosed disease and the fourth leading cause of death in the U.S. (American Diabetes Association, 2023).

Individuals with diabetes mellitus have impaired metabolism of carbohydrate, protein and fat as a result of abnormal production or utilization of insulin, the hormone secreted by the pancreas that controls blood sugar. When poorly controlled, diabetes leads to cardiovascular disease, retinal damage that could lead to blindness, peripheral nerve damage, and kidney damage.

There are several types of diabetes. Type 1 can occur at any age but is most commonly diagnosed from infancy to late 30s. In type 1 the pancreas produces little to no insulin, and the body's immune system destroys the insulin-producing cells in the pancreas. Type 2 diabetes typically develops after age 40, but has recently begun to appear with more frequency in children. Individuals with type 2 diabetes still produce insulin, but the body does not produce enough or is not able to use it effectively.

Type 1 diabetes is treated with insulin. Insulin administration may be done in several ways. The most common method is multiple daily injections (MDI) via a syringe and subcutaneous injection. For some individuals with diabetes, the use of multiple daily insulin injection therapy is insufficient to provide adequate control of blood sugar levels. In such cases, an external insulin pump may be recommended. These devices are worn externally and are attached to a temporary subcutaneous insulin catheter placed into the skin of the abdomen. The pump can be set to administer the insulin at a set (basal) rate or provide injections (bolus) as needed. The pump typically has a syringe reservoir that has a 2- to 3-day insulin capacity. The purpose of the insulin pump is to provide an accurate, continuous, controlled delivery of insulin which can be regulated by the user to achieve glucose control.

Since the publication of the Diabetes Control and Complication Trial (1993), there has been a growing body of evidence to suggest that improved blood glucose control in diabetics leads to improved clinical outcomes, especially with regard to long-term diabetic complications. This has led to an approach of intensive diabetic management to maintain blood glucose to as near normal as possible over all hours of the day and over the life span of the individual. Implementation of this approach requires the individual to be capable of, and committed to, a day-to-day medical program of some complexity. It requires ongoing compliance with multiple daily glucose measurements and insulin injections accompanied by appropriate adjustments in insulin dose. Additionally, successful intensive diabetic management requires response to a variety of external factors including changes in diet, exercise and the presence of infection. Despite this complexity, many motivated individuals can, with adequate training and support, achieve significant improvements in glucose control using this approach. Both multiple daily insulin injections and continuous subcutaneous insulin infusion via an external pump are effective means of providing intensive diabetic management (DCCT Research Group, 1993). Controlled trials comparing these insulin delivery methods show that in most individuals overall blood glucose control is the same or slightly improved with insulin pump treatment.

However, in diabetics treated with insulin pumps, hypoglycemia is less frequent and nocturnal glucose control is improved.

The evidence supports the efficacy of the external insulin infusion pump for properly trained diabetics who are not well controlled on intensive, multi-dose insulin therapy. Benefits are seen in long-term control as shown by lowered glycosylated HbA1c levels. In addition, stability of blood glucose self-measurement values as well as surveyed functional status and quality of life outcomes have been shown to improve in individuals using continuous insulin pump therapy (Hirsch, 1990; Kitzmiller, 1991; Pickup, 2002; Selam, 1990; Grunberger, 2014).

The benefit of insulin pump use for individuals with type 2 diabetes was established by the results of the OpT2mise Study (Aronson, 2016; Conget, 2016; Reznik, 2014). This well designed and conducted randomized controlled trial (RCT) concluded that for individuals with poorly controlled type 2 diabetes despite MDI, use of an insulin pump can be a valuable treatment option.

While standard insulin pumps operate on electricity, mechanical disposable insulin pumps (for example, the V-Go) have been proposed as an alternative. The existing evidence addressing this device is mainly in the form of short-term, retrospective studies (Boonin, 2017; Johns, 2014; Lajara, 2016a and 2016b; Meade, 2021; Rosenfeld, 2012; Sutton, 2016; Winter, 2015). A comparative trial reported by Lajara (2015) involved 204 subjects using the V-Go device vs. MDI. As with the above-described study, significant improvements in HbA1c concentration and decreases in required insulin volume were reported (-1.58% at 27 weeks and, p<0.001 for both).

Raval and colleagues (2019) reported the results of a retrospective cohort study involving data derived from the HealthCore Integrated Research Database. The study looked at 118 matched pairs of individuals with type 2 diabetes undergoing treatment with either the V-Go wearable insulin pump or MDI with 12 months of data available. At the end of 12 months of treatment both cohorts were reported to have improvements in percent HbA1c ≤ 9%, but no differences between groups were noted (p<0.001 for V-Go group and p=0.046 for the MDI group; p=0.263 between groups). Insulin prescription fills were reported to be lower in the V-Go group (mean change: -0.8 vs. +1.8 fills, p<0.001). A decrease in insulin total daily dose during the last 6 months of follow-up was also reported in the V-Go group (mean change in insulin units per day: -29.2 vs. +5.8, p<0.001).

Grunberger (2020) reported the results of a prospective open label case series study initially involving 188 subjects with type 2 diabetes and suboptimal glycemic control (HbA1c ≥ 7%) treated with the V-Go device. At 12 months, 112 subjects (60%) remained in the study, with 66 still on V-Go device. The authors reported a mean decrease in HbA1c from baseline of - 0.64%; (p=0.003) and total daily dose of insulin of 12 units/day (p<0.0001) at 12 months. However, due to the high dropout rate and lack of blinding, the value of this data is uncertain.

At this time, the available data comparing addressing the V-Go device appears to demonstrate equivalent outcomes to standard battery-operated insulin pump devices.

Back-up Insulin Infusion Pumps

Modern external infusion pumps appear safe and reliable, and studies reviewed did not indicate a need for a "back-up" pump. If an insulin pump fails, an individual can and should revert to daily multiple injections until the pump is repaired or replaced.

Insulin Infusion Pump Reservoir Issues

Some pediatric individuals experience increased insulin requirements which exceed the capabilities of the insulin reservoir of their current external insulin pump. In such cases, it may be reasonable to replace their existing pump with a model that has a reservoir that meets their insulin requirements. Requests for this type of equipment upgrade would be reviewed individually taking into account the unique needs of the individual and capacity of existing equipment.

Major Specialty Medical Society Recommendations

The ADA Standards of Medical Care in Diabetes-2023 has recommendations regarding the use of continuous glucose monitoring. These recommendations state:

- **7.1 The type(s) and selection of devices should be individualized based on a person's specific needs, preferences, and skill level. In the setting of an individual whose diabetes is partially or wholly managed by someone else (e.g., young child or a person with cognitive impairment or dexterity, psychosocial, and/or physical limitations) the caregiver's skills and preferences are integral to the decision-making process.**
- **7.25 Insulin pump therapy alone with or without sensor-augmented pump low glucose suspend feature and/or automated insulin delivery systems should be offered for diabetes management to youth and adults on multiple daily injections with type 1 diabetes A or other types of insulin-deficient diabetes E who are capable of using the device safely (either by themselves or with a caregiver) and are not able to use or do not choose an automated insulin delivery system. The choice of device should be made based on the individual's circumstances, preferences, and needs. A**
- **7.26 Insulin pump therapy can be offered for diabetes management to youth and adults on multiple daily injections with type 2 diabetes who are capable of using the device safely (either by themselves or with a caregiver). The choice of device should be made based on the individual's circumstances, preferences, and needs. A**
- **14.21 Insulin pump therapy alone should be offered for diabetes management to youth on multiple daily injections with type 1 diabetes who are capable of using the device safely (either by themselves or with caregivers). The choice of device should be made based on the individual's and family's circumstances, desires, and needs. A**
- **14.72 Individuals treated with metformin, a glucagon-like peptide 1 receptor agonist, and long-acting insulin who do not meet glycemic targets should be moved to multiple daily injections with long-acting and prandial insulins or insulin pump therapy. E**
- **15.19 Either multiple daily injections or insulin pump technology can be used in pregnancy complicated by type 1 diabetes. C**

The AACE and American College of Endocrinology (ACE) published a position statement on the integration of insulin pumps and continuous glucose monitoring in patients with diabetes mellitus (Grunberger, 2018). This document states the following:

R2.7.1 The use of an insulin pump without CGM could be used to manage persons with diabetes who are achieving glycemic targets with minimal TBR, who report infrequent episodes of symptomatic hypoglycemia, and who are using SMBG on a regular basis (at least 4 times per day for persons with T1D). Grade B; Intermediate-High Strength of Evidence; BEL
R3.5.1 Clinicians should strongly consider the discontinuation of insulin pump therapy based on an individual's ability to use it effectively and safely or based on the personal preference of a person with diabetes to discontinue this insulin delivery modality. Grade A; Intermediate Strength of Evidence; BEL 1

Additionally, in 2023 the Endocrine Society published *Management of individuals with diabetes at high risk for hypoglycemia* (McCall, 2023). In this document they make the following recommendations:

Recommendation 2: We suggest using real-time continuous glucose monitoring (CGM) and algorithm-driven insulin pumps (ADIPs) rather than multiple daily injections (MDIs) with self-monitoring of blood glucose (SMBG) three or more times daily for adults and children with type 1 diabetes (T1D). (2⊕⊕OO)

Definitions

External insulin infusion pumps: A device that is worn externally and attached to a temporary subcutaneous insulin catheter. An integrated computer controls a pump mechanism that administers insulin at a set rate or provide bolus injections as needed.

Glycemic: Having to do with blood sugar (glucose) levels.

Glycemic control: The ability of an individual's body to control blood glucose concentrations within a specific physiologic range, either on its own or with the assistance of medical therapy.

Glycosylated hemoglobin (HbA1c) test: A laboratory test that provides the percentage of a specific type of modified hemoglobin in the blood. This test ascertains the level of diabetic blood glucose control over the past three to four months.

Interstitial glucose: Glucose present in the fluid present in spaces between the tissue cells of the body.

Type 1 diabetes: A condition characterized by the impaired or inability of the pancreas to produce insulin. Sometimes known as 'juvenile diabetes.'

Type 2 diabetes: A condition characterized by a person's body losing the ability to use insulin properly, a problem referred to as insulin resistance.

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The use of specific product names is illustrative only. It is not intended to be a recommendation of one product over another, and is not intended to represent a complete listing of all products available.

History

Status	Date	Action
New	11/09/2023	Medical Policy & Technology Assessment Committee (MPTAC) review. Initial document development. Moved content related to external insulin pumps from CG-DME-42 Continuous Glucose Monitoring Devices and External Insulin Infusion Pumps.