

External Insulin Infusion Pumps

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Health Equity Consideration

Health equity is the highest level of health for all individuals; health inequity is the avoidable difference in health status or distribution of health resources due to the social conditions in which individuals are born, grow, live, work, and age. Social determinants of health are the conditions in the environment that affect a wide range of health, functioning, and quality of life outcomes and risks. Examples include the following: safe housing, transportation, and neighborhoods; racism, discrimination, and violence; education, job opportunities, and income; access to nutritious foods and physical activity opportunities; access to clean air and water; and language and literacy skills.

Introduction

External insulin infusion pumps are addressed by this guideline.

Criteria

An external insulin pump and related supplies are considered medically necessary when an individual meets **all** of the following initial coverage criteria:

- The individual has type 1 or type 2 diabetes mellitus.
- The individual uses insulin to manage their diabetes and requires multiple (three or more) daily injections with frequent self-adjustments of insulin dose for at least six months prior to initiation of the insulin pump.
- The individual checks their blood glucose at least four times a day or uses a continuous glucose monitor (CGM).
- There is documentation of **any** of the following:
 - The individual has a glycated hemoglobin (HbA1c) greater than 7% despite adherence to the prescribed diabetes treatment plan.
 - The individual has fasting blood sugars in the morning greater than 200mg/dl. (dawn phenomenon).
 - The individual has a history of frequent low blood sugar readings less than 70 mg/dl.
 - The individual has a history of problems with high or low blood sugar levels before mealtime.

- The individual has difficulty achieving or maintaining glycemic control with the current insulin regimen.
- The individual has ongoing participation in a diabetes management program.

Note:

Refer to the Medical Background FDA approval manufacturer age specifications.

Supplies

When an external insulin infusion pump is considered medically necessary, all associated supplies required for its effective use are also considered medically necessary.

Not Covered

- The following devices are not covered as they do not meet the definition of durable medical equipment (DME):
 - An implanted infusion pump for the infusion of insulin to treat diabetes.
 - A disposable external insulin infusion pump and related supplies.

Background and Supporting Information

Glycated hemoglobin (HbA1c) is a blood test that reflects average glycemia over the lifespan of the red blood cell (100 to 120 days), however 50% of HbA1c is determined by glycemia during the month preceding measurement. HbA1c monitors long-term glycemic control and provides an indication of the average of blood glucose levels over the preceding three months. Increased HbA1c is associated with an increased risk of long-term complications.

Blood glucose monitoring (BGM) devices measure the glucose level of a small amount of blood (usually from the fingertip), typically three to four times per day. BGM readings look at specific glucose values at specific points in time, generating a pattern of variability.

Continuous glucose monitoring (CGM) devices measure the glucose content of interstitial fluid every five to 15 minutes, depending on the device. CGM systems provide visualization of the current glucose value as well as trend arrow analysis, which indicates the direction of changing glucose. This technology can help individuals fine-tune diabetic treatment.

Evidence Discussion

A 2023 review (Bassi et al.) evaluated automated insulin delivery systems, including external insulin infusion pumps with automated basal adjustment and correction capabilities, with a focus on their clinical effectiveness across pediatric and adult populations with type 1 diabetes mellitus (T1DM) and selected other forms of diabetes. Across randomized trials and real-world studies summarized by the authors, use of these external insulin infusion pumps was consistently associated with improved glycemic outcomes compared with prior therapies. Reported benefits included increases in time in range, typically by approximately 8% to 12%, reductions in glycated hemoglobin of about 0.4% to 0.6%, and maintenance of low time below range, often at or below 2%. Large observational cohorts involving more than 4,000 individuals demonstrated sustained improvements in routine clinical use, including mean time in range exceeding 75% and glucose management indicator values below 7%, without an associated increase in hypoglycemia. The authors concluded that external insulin infusion pumps with automated basal adjustment and correction capabilities were effective, safe, and adaptable across age groups and clinical settings and represented a significant advancement in diabetes management that supported their continued use in the home. Limitations included heterogeneity among included studies, limited long-term outcome data, reliance on observational real-world evidence for newer pump systems, and fewer randomized controlled trials in certain subpopulations.

Alotaibi et al. (2020) performed a systematic review and meta-analysis to evaluate the effectiveness and safety of predictive low-glucose suspend (PLGS) in children and adolescents with type 1 diabetes mellitus (T1DM). The analysis included five randomized controlled trials with a total sample size of 493 children aged 6 to 18 years that compared PLGS versus sensor-augmented pumps (SAP). The authors reported high quality evidence that PLGS is superior to SAP in decreasing time spent in hypoglycemia, without increasing percentage of time spent in hyperglycemia or episodes of diabetic ketoacidosis (DKA). In summary, the authors concluded that PLGS was superior to SAP in decreasing daytime and nocturnal hypoglycemia without increasing the risk of DKA or hyperglycemia.

A 2024 systematic review and meta analysis (Roos et al.) evaluated 62 studies (n=9253) that included individuals using automated insulin delivery systems and reported outcomes across 45 different questionnaires. Randomized controlled trials demonstrated reduced diabetes distress with a standardized mean difference of -0.159 and reduced fear of hypoglycemia with a standardized mean difference of -0.339. Improvements were also observed in hypoglycemia unawareness with a standardized mean difference of -0.231 and in overall quality of life, where adults demonstrated a standardized mean difference of 0.347 and children and adolescents demonstrated a standardized mean difference of 0.249. The authors concluded that automated insulin delivery was associated with reduced psychosocial burden and improved well being.

Study limitations included substantial heterogeneity in measurement tools, variation in study designs, and insufficient numbers of studies for pooling certain outcomes, which limited the certainty of some findings.

In a multicenter randomized controlled trial, Brown et al. (2019) evaluated the effectiveness of closed-loop systems that automate insulin delivery to improve glycemic outcomes in individuals with type 1 diabetes mellitus (T1DM). The study randomized 168 individuals (ages 14 to 71) with T1DM to receive treatment with a closed-loop system (closed-loop group) or a sensor-augmented pump (SAP) (control group). The primary outcome was the percentage of time that the blood glucose level was within the target range of 70 to 180 mg per deciliter as measured by continuous glucose monitoring (CGM). The mean percentage of time that the glucose level was within the target range increased in the closed-loop group from $61\pm 17\%$ at baseline to $71\pm 12\%$ during the six months and remained unchanged at $59\pm 14\%$ in the control group ($P<0.001$). No serious hypoglycemic events occurred in either group; one episode of diabetic ketoacidosis occurred in the closed-loop group. Thus, the authors concluded that compared to the use of SAP, a closed-loop system was associated with a greater percentage of time spent in a target glycemic range.

In 2020, Breton and colleagues reported on a multicenter randomized controlled trial that evaluated the effectiveness of a closed-loop system of insulin delivery (artificial pancreas) on glycemic outcomes in children with type 1 diabetes mellitus (T1DM). The study randomized 101 children aged six to 13 years old with T1DM to receive treatment with a closed-loop system of insulin delivery (closed-loop group) or a sensor-augmented insulin pump (SAP) (control group). The primary outcome was the percentage of time that the glucose level was in the target range of 70 to 180 mg per deciliter, as measured by continuous glucose monitoring (CGM). At 16 weeks, the mean percentage of time that the glucose level was in the target range of 70 to 180 mg per deciliter increased from $53\pm 17\%$ at baseline to $67\pm 10\%$ in the closed-loop group and from $51\pm 16\%$ to $55\pm 13\%$ in the control group ($P<0.001$). In both groups, the median percentage of time that the glucose level was below 70 mg per deciliter was low (1.6% in the closed-loop group and 1.8% in the control group). In the closed-loop group, the median percentage of time that the system was in the closed-loop mode was 93%. No episodes of diabetic ketoacidosis or severe hypoglycemia occurred in either group. The authors found that glucose levels were in the target range for a greater percentage of time in individuals who used a closed-loop system of insulin delivery system compared with those who used an SAP. Moreover, there were no significant differences in HbA1c changes between the groups.

A 2020 randomized controlled trial (McAuley et al.) investigated glycemic and psychosocial outcomes with hybrid closed-loop (HCL) versus user-determined insulin dosing with multiple daily injections (MDI) or insulin pump. One hundred-twenty adults with type 1 diabetes mellitus (T1DM) using MDI or an insulin pump without continuous glucose monitoring (CGM) were randomized to 26 weeks of HCL or continuation of

current therapy. The primary outcome was CGM time in range (TIR; 70–180 mg/dL) during the final three weeks. HCL TIR increased from 55% (SD 13%) at baseline to 70% (SD 10%) at 26 weeks. The control group was unchanged from baseline (55%, SD 12%) to 26 weeks (55%, SD 13%) ($P < 0.0001$). In addition, the HCL group had a lower HbA1c level. Seventeen (nine device-related) versus 13 serious adverse events occurred in the HCL and control groups, respectively. In summary, at six-month follow-up, hybrid closed-loop insulin delivery was associated with an increased percentage of time in range, decrease in HbA1c level, and improved diabetes-specific quality of life compared with manual insulin dosing.

In 2021, a multicenter single-arm prospective study by Brown and colleagues evaluated the efficacy and safety of a tubeless on-body automated insulin delivery system in 235 children and adults with type 1 diabetes mellitus (T1DM). A 2-week standard therapy phase (usual insulin regimen) was followed by three months of automated insulin delivery. Primary safety outcomes were incidence of severe hypoglycemia and diabetic ketoacidosis. Primary effectiveness outcomes were change in HbA1c and percent time in range (70–180 mg/dL). At three-month follow-up, HbA1c was significantly reduced in children by 0.71% (7.8 mmol/mol) ($P < 0.0001$) and in adults by 0.38% (4.2 mmol/mol) ($P < 0.0001$). Time in range was improved from standard therapy by $15.6 \pm 11.5\%$ in children and $9.3 \pm 11.8\%$ in adults ($P < 0.0001$). Thus, at three-month follow-up, the use of the tubeless automated insulin delivery system was associated with a reduction in HbA1c, an improvement in time in range, and low incidence rates of severe hypoglycemia.

In 2022, Choudhary and colleagues reported on a multicenter, randomized controlled trial (The Advanced Hybrid Closed Loop Study in Adult Population with Type 1 Diabetes (ADAPT) trial) to assess the efficacy of advanced hybrid closed loop (AHCL) systems compared with current therapy. Eighty-two adults with T1DM using multiple daily injections of insulin and intermittently scanned continuous glucose monitoring (isCGM) with HbA1c of at least 8% were randomized to one of two cohorts: multiple daily injections of insulin plus isCGM (cohort A), or real time continuous glucose monitoring (cohort B). At six-month follow-up, mean HbA1c level had decreased by 1.54% (from 9.00% to 7.32%) in the AHCL group and by 0.20% (9.07% to 8.91%) in the multiple daily injections of insulin plus isCGM group. Thus, the authors concluded that in individuals with T1DM using multiple daily injections of insulin plus isCGM and with HbA1c of at least 8%, the use of AHCL conferred benefits in terms of glycemic control beyond those that could be achieved with multiple daily injections of insulin plus isCGM.

A multicenter, randomized controlled trial (OpT2mise) (Reznik et al., 2014) compared the efficacy of pump treatment and multiple daily injections for lowering glucose in insulin-treated individuals with type 2 diabetes mellitus (T2DM). The study randomized 331 individuals with T2DM with poor glycemic control to insulin pump treatment or continued multiple daily injections of insulin. The primary endpoint was change in mean glycated hemoglobin (HbA1c) level between baseline and end of the randomized

phase for the intention-to-treat population. At six months, individuals treated with an insulin pump had a mean reduction in HbA1c of 1.1%, as compared with a reduction of 0.4% in the multiple daily injection group ($p<0.0001$); moreover, there was not an associated increase in hypoglycemia. Two diabetes-related serious adverse events (hyperglycemia or ketosis without acidosis) resulting in hospital admission occurred in the pump treatment group compared with one in the multiple daily injection group. No ketoacidosis occurred in either group and one episode of severe hypoglycemia occurred in the multiple daily injection group. Thus, the authors concluded that in individuals whose T2DM is poorly controlled despite using multiple daily injections of insulin, pump treatment could be considered as a safe and valuable treatment option.

Pickup et al. (2017) conducted a systematic review and meta-analysis to compare glycemic control during continuous subcutaneous insulin infusion (CSII) and multiple daily insulin injections (MDI) in individuals with type 2 diabetes mellitus (T2DM). The authors identified five randomized trials that compared mean glycated hemoglobin (HbA1c) level during CSII versus MDI in individuals with T2DM. The primary outcome was glycemic control at study completion, as measured by HbA1c level. The authors reported that insulin pump therapy achieves better glycemic control than MDI in participants with poorly controlled T2DM at baseline; moreover, the greatest effect was noted in individuals with the highest baseline HbA1c levels and insulin doses.

In a crossover trial, El-Khatib et al. (2017) aimed to assess whether a bihormonal bionic pancreas initialized only with body mass index (BMI) can safely reduce mean glycemic level in adults with type 1 diabetes mellitus (T1DM). Forty-three adults received therapy with automated, bihormonal, closed-loop system for 11 days and therapy with their own insulin pump for 11 days. The primary outcomes were the mean glucose concentration and time with continuous glucose monitoring (CGM) glucose concentration less than 3.3 mmol/L, analyzed over days two through 11. The mean CGM glucose concentration was 7.8 mmol/L in the bionic pancreas period versus 9.0 mmol/L in the comparator period ($p<0.0001$). The mean time with CGM glucose concentration less than 3.3 mmol/L was 0.6% in the bionic pancreas period versus 1.9% in the comparator period ($p<0.0001$). There were no serious or unexpected adverse events in the bionic pancreas period of the study. The authors concluded that relative to conventional and SAP therapy, the bihormonal bionic pancreas was able to achieve superior glycemic regulation without the need for carbohydrate counting. However, the authors noted that additional studies were needed to establish the long-term benefits and risks of automated glycemic management with a bihormonal bionic pancreas.

The 2024 American Diabetes Association (ADA)'s "Standards of Care in Diabetes-2024" clinical practice recommendations for the treatment and management of diabetes mellitus recommended:

- "AID systems should be offered for diabetes management to youth and adults with type 1 diabetes mellitus and other types of insulin-deficient 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."

- "Insulin pump therapy alone with or without a sensor-augmented pump low-glucose suspend feature should be offered for diabetes management to youth and adults on MDI with type 1 diabetes mellitus or other types of insulin-deficient diabetes who are capable of using the device safely (either by themselves or with a caregiver), and who are not able to use or do not choose an AID system. The choice of device should be made based on the individual's circumstances, preferences, and needs."
- "Insulin pump therapy can be offered for diabetes management to youth and adults on MDI with type 2 diabetes mellitus 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."

Codes Addressed in this Guideline

The inclusion of any code in this table does not imply that the code is under management or requires prior authorization. Refer to the applicable health plan for management details. Prior authorization of a code listed in this table is not a guarantee of payment. The Certificate of Coverage or Evidence of Coverage policy outlines the terms and conditions of the member's health insurance policy.

HCPSC Code	Description
A4224	Supplies for maintenance of insulin infusion catheter, per week
A4225	Supplies for external insulin infusion pump, syringe type cartridge, sterile, each
A4230	Infusion set for external insulin pump, non-needle cannulas type
A4231	Infusion set for external insulin pump, needle cannulas type
A4232	Syringe with needle for external insulin pump, sterile, 3 cc
A4238	Supply allowance for adjunctive, non-implanted continuous glucose monitor (cgm), includes all supplies and accessories, 1 month supply = 1 unit of service
A4239	Supply allowance for non-adjunctive, non-implanted continuous glucose monitor (cgm), includes all supplies and accessories, 1 month supply = 1 unit of service
A9274	External ambulatory insulin delivery system, disposable, each, includes all supplies and accessories

HCP Code	Description
E0782	Infusion pump, implantable, non-programmable (includes all components, e.g., pump, catheter, connectors, etc.)
E0784	External ambulatory infusion pump, insulin
E0785	Implantable intraspinal (epidural/intrathecal) catheter used with implantable infusion pump, replacement
E0786	Implantable programmable infusion pump, replacement (excludes implantable intraspinal catheter)

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