MEDICAL POLICY

Diabetes: Insulin Infusion Pumps
(External and Implanted)
(All Lines of Business Except Medicare)

Effective Date: 5/1/2020

Section: DME
Policy No: 208

Technology Assessment Committee Approved Date: 3/13
Medical Policy Committee Approved Date: 8/02; 11/02; 8/03; 5/04; 3/05; 7/05; 1/06; 3/07; 7/07; 5/09; 7/11; 4/13; 9/13; 6/14; 8/15; 4/16; 12/16; 8/17; 1/18; 1/19; 11/19; 2/20

Medical Officer
Date

See Policy CPT/HCPCS CODE section below for any prior authorization requirements

SCOPE:

Providence Health Plan, Providence Health Assurance, Providence Plan Partners, and Ayin Health Solutions as applicable (referred to individually as “Company” and collectively as “Companies”).

APPLIES TO:

All lines of business except Medicare

BENEFIT APPLICATION

Medicaid Members

Oregon: Services requested for Oregon Health Plan (OHP) members follow the OHP Prioritized List and Oregon Administrative Rules (OARs) as the primary resource for coverage determinations. Medical policy criteria below may be applied when there are no criteria available in the OARs and the OHP Prioritized List.

POLICY CRITERIA

Notes:

- Type 1 diabetes is not addressed in this policy. The use of insulin infusion pumps (external and implanted) in Type 1 diabetics may be considered medically necessary and covered.
- This policy does not address integrated insulin pump and glucose monitoring systems. These systems require prior authorization for both Type 1 and Type 2 diabetics and are addressed in our Diabetes: Integrated Insulin Infusion and Glucose Monitoring Systems (All Lines of Business Except Medicare), DME112, medical policy.

External Infusion Pump and Related Accessories and Supplies (Initial Use)
I. Initial use of an external infusion pump and related accessories, supplies, and insulin for administration of continuous subcutaneous insulin in Type 2 diabetics may be considered medically necessary and covered when the following criteria (A.-E.) are met:

   A. The patient has completed a comprehensive diabetes education program; and
   B. The patient has been on a program of multiple daily injections of insulin (i.e., at least 2 injections per day); and
   C. The patient has either a documented ability to self-adjust insulin dose for at least 6 months prior to initiation of the insulin pump, or has a documented ability to successfully use a continuous glucose monitor; and
   D. The patient has a documented ability to glucose self-test at least four times daily while on insulin; and
   E. The patient meets at least one of the following criteria (1.- 5.) while on the multiple injection regimen:
      1. Glycosylated hemoglobin level (HbA1C) greater than 7%; or
      2. History of recurring, symptomatic hypoglycemia; or
      3. Fasting blood sugars frequently exceeding 200 mg/dL; or
      4. History of severe glycemic fluctuations; or
      5. Documented need for more than 5 daily injections of insulin.

II. An external infusion pump and related accessories, supplies, and insulin are considered not medically necessary and are not covered if criterion I. above is not met, including, but not limited to gestational diabetes.

Disposable Drug Delivery Systems

IV. Disposable external insulin pumps with wireless communication capability to a hand-held control unit (e.g., OmniPod®, V-Go®) is an acceptable alternative to a standard insulin infusion pump and considered medically necessary and is covered if criterion I. above is met.

Implantable Infusion Pump

V. An implanted infusion pump for the infusion of insulin to treat diabetes is considered investigational and is not covered.

Enhancements/Optional Accessories

VI. Enhancements or optional accessories for insulin pumps via smartphones, tablets and computers are considered convenience items and therefore are not medically necessary and are not covered, including, but not limited to:
   • Mobile Apps (e.g., t:connect®)
## MEDICAL POLICY

### Diabetes: Insulin Infusion Pumps

*(External and Implanted)*

*(All Lines of Business Except Medicare)*

- Diabetes management software (e.g., Medtronic CareLink® system)
- Remote monitoring devices (e.g., mySentry)

### Replacement of External Insulin Pumps

VII. Replacement of an existing external insulin pump may be considered **medically necessary and covered** when either one of the following criteria (A.-B.) is met:

A. The patient has a documented need for a larger insulin reservoir; or

B. Documentation that **at least one** of the device components meet **all** of the following criteria (1.-3.):
   1. Are no longer functional; and
   2. Are not under warranty; and
   3. Cannot be repaired.

VIII. Replacement of an existing external insulin pump is considered **not medically necessary and not covered** when criterion VII. above is not met.

IX. Replacement of an existing functional external insulin pump for convenience or aesthetic purposes (e.g., wireless communication component) is considered **not medically necessary and is not covered**.

## BILLING GUIDELINES

HCPCS codes A9274 (external ambulatory insulin delivery system, disposable) or E0784 (external ambulatory infusion pump, insulin) only require prior authorization for the use of insulin infusion pumps in Type 2 diabetics. This includes all of the following diagnosis codes:

- E11
- E11.0
- E11.1
- E11.2
- E11.3
- E11.4
- E11.5
- E11.6
- E11.8
- E11.9

## CPT/HCPCS CODES

### All Lines of Business Except Medicare

**Prior Authorization Required**

*Note: prior authorization only required for type 2 diabetes diagnoses (see billing guidelines for complete ICD-10 list)*
DESCRIPTION

Insulin pumps are devices used to deliver insulin in a programmed and controlled manner to diabetic individuals by way of continuous subcutaneous insulin infusion (CSII). These devices work with a separate glucometer through manual or remote functions. The goals of insulin pump therapy are to achieve near-normal control of blood glucose levels. They are proposed as an alternative to administering insulin via multiple daily injections (MDI) and are thought to improve metabolic control in people with diabetes. Insulin pumps are categorized as follows:

1. External insulin pumps are devices which deliver insulin via subcutaneous or intraperitoneal routes.
These devices are traditionally worn on a belt or kept in a pocket with tubing connecting the pump to the infusion set. Newer devices contain components with varying degrees of wireless connectivity, some of which may be worn directly on the skin. In addition, external insulin pumps may be either disposable or have disposable components, but both types are programmable. However, separate from pumps, patch devices deliver preset dosages of insulin transdermally and lack programmability. The following are examples of FDA cleared external insulin delivery systems:

Conventional:
- Accu-Chek® Aviva Combo System (Roche Diagnostics)
- t:flex (Tandem Diabetes Care, Inc.)

Disposable:
- OmniPod System (Insulet) (wireless and programmable, but has disposable components)
- V-Go™ Disposable Insulin Delivery Device (Valeritas, Inc.) (non-programmable patch)
- Finesse™ Personal Insulin Delivery Patch (Calibra Medical, Inc.) (non-programmable patch)

2. Implantable insulin pumps deliver insulin via intraperitoneal or intravenous routes. Currently, there are no implantable insulin infusion pumps that are approved by the FDA. However, some devices have been granted Investigational Device status.

REVIEW OF EVIDENCE

A review of the ECRI, Hayes, Cochrane, and PubMed databases was conducted regarding the use of insulin pumps as a treatment for type 2 diabetes. Below is a summary of the available evidence identified through November 2019.

Type 2 Diabetes Patients

Systematic Reviews

- In 2018, Hayes published a systematic review evaluating the safety and efficacy of the V-Go disposable insulin delivery device for the management of type 1 or type 2 diabetes mellitus.\textsuperscript{1} Searching the literature through September 2018, investigators identified 2 poor-quality retrospective cohort study assessing V-Go in the treatment of 116 patients with type 2 diabetes. In the larger study, patients on basal insulin injections with baseline HbA1c levels of 7% to 14% were switched to either V-Go or basal-bolus insulin injections. While both groups experienced significant improvements from baseline at 7-month follow-up, V-Go patients experienced significantly greater reductions in HbA1c values (−0.64; 95% CI, -1.17 to -0.10; \( p = 0.02 \)). Limitations included the study’s small sample size, retrospective design, variable follow-up durations and author conflicts of interest with the device manufacturer. A smaller study assessing 23 patients reported similar results at 12-week follow-up.
Given the very-low quality of evidence, authors concluded that evidence did not allow for conclusions to be drawn regarding the safety or efficacy of the V-Go system. While early results indicate that V-Go may improve patients’ glycemic control as measured by reductions in hemoglobin A1c levels, substantial uncertainty remains given the limited number of studies conducted to date, lack of long-term follow-up, unclear patient selection criteria and small sample sizes. Investigators concluded that V-Go “may be a good option for patients with poorly controlled type 2 diabetes,” but ultimately assigned the system a “D2” rating (insufficient evidence).

- In 2012, the Agency for Healthcare and Research Quality published a comparative effectiveness review of methods of insulin delivery which focused, in part, on type 2 diabetics. The review included three RCTs of 6-12 months duration and one crossover trial published prior to July 2011, with no significant heterogeneity found between studies. Studies reported no difference in the effect of continuous subcutaneous insulin infusion (CSII) and multiple daily insulin injections (MDI) on HbA1c (moderate strength of evidence [SOE]), severe hypoglycemia (low SOE) or hyperglycemia (low SOE) for adults with type 2 diabetes. The evidence was insufficient to make definitive conclusions about the relative effects of these therapies on hyperglycemia and weight. In general, the existing studies were small and of fair to poor quality. The review concluded that both CSII and MDI have similar effectiveness on glycemic control and severe hypoglycemia in type 2 diabetics and therefore the approach to intensive insulin therapy could be individualized to patient preference that would maximize their quality of life.

- A second systematic review was published by Yeh et al. that also included the same four trials and arrived at similar conclusions.

Randomized Controlled Trials (RCTs)

- In 2014, Reznik et al. published results from the industry-sponsored open-label OpT2mise RCT which compared CSII with MDI for treatment of type 2 diabetes. Patients with type 2 diabetes who had poor glycemic control despite MDI with insulin analogues were enrolled into a 2-month dose-optimization run-in period. After the run-in period, patients with HbA1c of 8.0-12.0% were randomly assigned (1:1) to pump treatment or to continue with multiple daily injections. Neither patients nor investigators were masked to treatment allocation. In the intent to treat population, 495/590 screened patients entered the run-in phase and 331 were randomized (168 to CSII, 163 to MDI). At six months post-randomization, mean HbA1c had decreased by 1.1% (SD 1.2%) in the CSII group and 0.4% (SD 1.1%) in the MDI, resulting in a significant between-group difference of -0.7% (95% CI -0.9 to -0.4%; p<0.0001). In addition, the mean total daily insulin dose was 97 units (SD 56) in the CSII group versus 122 units (SD 68) for MDI (p<0.0001), with no significant difference in bodyweight change between the two groups. There was no significant difference between groups in the number diabetes-related serious adverse events. Limitations of this RCT included lack of blinding of patients and investigators, exclusion of patients with high daily insulin doses, actual dose of insulin could not be assessed, and the finding that patients in
the MDI group showed a decrease in their daily frequency of self-monitoring during the treatment phase, which may have impacted insulin dosing.

- In 2016, Aronson et al.\textsuperscript{5} published results at 12-month follow-up of the OpT2mise RCT discussed above.\textsuperscript{4,5} During the six months randomization phase of the OpT2mise trial the MDI group was switched to CSII. The pump therapy group maintained their HbA1c improvement at 12 months while the MDI group, which was switched to pump therapy, showed a 0.8% reduction, with the final HbA1c level being identical in both arms. Total daily insulin dose (TDD) in the pump group remained stable at 12 months. The MDI-pump group showed a 19% decline in TDD, such that by 12 months TDD was equivalent in both groups. The investigators concluded that the pump therapy has a sustained durable effect on glycemic control in type 2 diabetes.

**Summary**

There is insufficient evidence regarding the use of CSII in type 2 diabetic patients is as effective in controlling glycemia as MDI. The majority of RCTs published to date have reported no difference in the effect of CSII and MDI on HbA1c, severe hypoglycemia or hyperglycemia for adults with type 2 diabetes. While this could indicate that the two methods of insulin administration may be equal, these RCTs were small in number, moderate quality and typically reported on small sample sizes. At this time definitive conclusions about the effectiveness of CSII compared to MDI in type 2 diabetic patients cannot be drawn.

**CLINICAL PRACTICE GUIDELINES**

**Type 2 Diabetes Patients**

*Endocrine Society*

In 2016, the Endocrine Society conducted a systematic review in support of their clinical practice guidelines addressing the use of continuous subcutaneous insulin infusion (CSII) for the treatment of diabetes.\textsuperscript{6} Authors recommended CSII with good adherence to monitoring and dosing patients with type 2 diabetes mellitus who have poor glycemic control despite intensive insulin therapy, oral agents, other injectable therapy and lifestyle modifications.

*National Institute for Health and Care Excellence (NICE)*

The 2015 NICE guideline, “Type 2 Diabetes in Adults: Management”\textsuperscript{7}, did not address the use of an insulin pump as a treatment option for type 2 diabetic adults. However, the 2008 Tech Appraisal Guidance [TA151]: Continuous subcutaneous insulin infusion (CSII) for the treatment of diabetes mellitus,\textsuperscript{8} recommended against the use of insulin pumps for treatment of type 2 diabetic patients of any age.
In 2014, the AACE/ACE published a clinical practice guideline addressing insulin pump use for the treatment of diabetes. The guideline included a recommendation for the use of continuous subcutaneous insulin infusion, stating that ideal CSII candidates include intensively managed insulin-dependent type 2 diabetics who meet the following criteria:

- Currently performing ≥ 4 insulin injections and ≥ 4 self-monitored blood glucose measurements daily
- Motivated to achieve optimal blood glucose control
- Willing and able to carry out the tasks that are required to use this complex and time consuming therapy safely and effectively
- Willing to maintain frequent contact with their health care team

**Pediatric Patients**

*International Society for Pediatric and Adolescent Diabetes (ISPAD)*

The 2014 ISPAD evidence-based clinical practice consensus guideline: Assessment and Monitoring of Glycemic Control in Children and Adolescents with Diabetes stated that, “improvements in glycemic control, particularly when provided by intensive insulin treatment with multiple daily injections (MDI) or pump therapy with dose adjustments, reduces the risks of vascular complications.” This statement was based on a combination of high quality evidence from well-conducted RCTs and expert consensus.

In the guideline, the ISPAD also stated that, “insulin pump therapy is at present the best way to imitate the physiological insulin profile” and that, “CSII has been proven to be safe in all ages and allows exact and flexible insulin dosing in small increments, multiple bolus dosing without need for injections, different prandial bolus options, and hourly adaptation of basal insulin.”

*National Institute for Health and Care Excellence (NICE)*

The 2015 NICE guideline, “Diabetes (Type 1 and Type 2) in Children and Young People: Diagnosis and Management”, regarding children under the age of 18, recommended criteria based on the 2008 Tech Appraisal Guidance [TA151]. The NICE recommendations for CSII therapy were as follows:

- “Continuous subcutaneous insulin infusion (CSII or 'insulin pump') therapy is recommended as a treatment option for adults and children 12 years and older with type 1 diabetes mellitus provided that:
  - Attempts to achieve target HbA1c levels with MDIs result in the person experiencing disabling hypoglycaemia. (disabling hypoglycaemia is defined as the repeated and
unpredictable occurrence of hypoglycaemia that results in persistent anxiety about recurrence and is associated with a significant adverse effect on quality of life; or
  o HbA1c levels have remained high (8.5% or above) on MDI therapy (including, if appropriate, the use of long-acting insulin analogues) despite a high level of care.

- For children younger than 12 years with type 1 diabetes mellitus CSII therapy is recommended as a treatment option when MDI therapy is considered to be impractical or inappropriate.
- For children between the ages of 12 and 18 years the same criteria for adults for CSII apply, but these children are also expected to undergo a trial of MDI therapy prior to CSII.
- It is recommended that CSII therapy be initiated only by a trained specialist team, which should normally comprise a physician with a specialist interest in insulin pump therapy, a diabetes specialist nurse and a dietitian. Specialist teams should provide structured education programmes and advice on diet, lifestyle and exercise appropriate for people using CSII.
- Following initiation in adults and children 12 years and older, CSII therapy should only be continued if it results in a sustained improvement in glycaemic control, evidenced by a fall in HbA1c levels, or a sustained decrease in the rate of hypoglycaemic episodes. Appropriate targets for such improvements should be set by the responsible physician, in discussion with the person receiving the treatment or their carer.
- CSII therapy is not recommended for the treatment of people (children or adults) with type 2 diabetes mellitus.”

Pregnant Women

*American Diabetes Association (ADA)*

In 2019, the ADA published a clinical practice guideline addressing the management of diabetes during pregnancy. Authors stated “both multiple daily insulin injections and continuous subcutaneous insulin infusion are reasonable delivery strategies” with neither having been proven superior during pregnancy.

*National Institute for Health and Care Excellence (NICE)*

The NICE 2015 guideline, Diabetes in Pregnancy: Management from Preconception to the Postnatal Period recommended the following:

“Offer women with insulin-treated diabetes continuous subcutaneous insulin infusion (CSI; also known as insulin pump therapy) during pregnancy if adequate blood glucose control is not obtained by MDI without significant disabling hypoglycaemia. Disabling hypoglycaemia means the repeated and unpredicted occurrence of hypoglycaemia requiring third-party assistance that results in continuing anxiety about recurrence and is associated with significant adverse effect on quality of life.”

The NICE guideline further states that:
“Compared with MDI, CSII used during pregnancy in women with overt diabetes provides comparable or better glycemic control and pregnancy outcomes with no greater risk or possibly lower risk of maternal hypoglycemia. Additionally, compared with MDI, CSII provides greater lifestyle flexibility, easier blood glucose management, less blood glucose variability, and facilitates managing glucose control in the peri-delivery setting.”

Endocrine Society

The 2013 Endocrine Society evidence-based clinical practice guideline on diabetes and pregnancy\textsuperscript{13} recommended the, “ongoing use of CSII during pregnancy in women with diabetes when this has been initiated before pregnancy (strong recommendation, moderate quality evidence), but suggest that CSII not be initiated during pregnancy unless other insulin strategies including multiple daily doses of insulin have first been tried and proven unsuccessful.” This was a weak recommendation based on low quality evidence. The guideline states that this refers to both type 1 and type 2 diabetic patients.

INSTRUCTIONS FOR USE

Company Medical Policies serve as guidance for the administration of plan benefits. Medical policies do not constitute medical advice nor a guarantee of coverage. Company Medical Policies are reviewed annually and are based upon published, peer-reviewed scientific evidence and evidence-based clinical practice guidelines that are available as of the last policy update. The Companies reserve the right to determine the application of Medical Policies and make revisions to Medical Policies at any time. Providers will be given at least 60-days’ notice of policy changes that are restrictive in nature.

The scope and availability of all plan benefits are determined in accordance with the applicable coverage agreement. Any conflict or variance between the terms of the coverage agreement and Company Medical Policy will be resolved in favor of the coverage agreement.

REGULATORY STATUS

Mental Health Parity Statement

Coverage decisions are made on the basis of individualized determinations of medical necessity and the experimental or investigational character of the treatment in the individual case.

MEDICAL POLICY CROSS REFERENCES

- Diabetes: Insulin Infusion Pumps – External and Implanted (Medicare Only), DME414
- Diabetes: Integrated Insulin Infusion and Glucose Monitoring Systems (All Lines of Business Except Medicare), DME112
- Diabetes: Integrated Insulin Infusion and Glucose Monitoring Systems (Medicare Only), DME397
MEDICAL POLICY

Diabetes: Insulin Infusion Pumps
(External and Implanted)
(All Lines of Business Except Medicare)

- Diabetes: Blood Glucose Monitor and Supplies, DME206
- Diabetes: Continuous Glucose Monitors (All Lines of Business Except Medicare), DME207
- Diabetes: Continuous Glucose Monitors (Medicare Only), DME392

REFERENCES

Medical Policy

Diabetes: Insulin Infusion Pumps (External and Implanted)
(All Lines of Business Except Medicare)

