PROVIDENCE HEALTH PLANS AND PROVIDENCE HEALTH ASSURANCE MEDICAL POLICY

Diabetes: Insulin Infusion Pumps (External and Implanted)

Effective Date: 2/1/2019

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

Medical Officer Date

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

APPLIES TO:

All lines of business

BENEFIT APPLICATION

Medicaid Members

Oregon: Services requested for Oregon Health Plan (OHP) members follow the OHP Prioritized List and Oregon Administrative Rules (OARs) for coverage determinations.

For other lines of business, refer to the Policy Criteria section below:

POLICY CRITERIA

This policy is primarily based on the Centers for Medicare & Medicaid Services National Coverage Determination (NCD) for Infusion Pumps (280.14), Local Coverage Determination (LCD) L33794: External Infusion Pumps, and Local Coverage Article (LCA) A52507: External Infusion Pumps - Policy Article.¹⁻³

External Infusion Pump and Related Accessories and Supplies (Initial Use)

1. Initial use of an external infusion pump and related accessories, supplies, and insulin for administration of continuous subcutaneous insulin may be considered medically necessary and covered for the treatment of non-pregnant adult*, diabetic (type 1 or 2 for Medicare members and type 1 for non-Medicare members) patients if criterion A. or B. is met and if criterion C. is met:

*NOTES:
- Adult is defined as 18 years and older.
- C-peptide levels OR beta cell autoantibody test results only need to be documented once in the medical records for initial use.

A. C-peptide testing requirement – must meet criterion 1. or 2. and criterion 3.:
1. C-peptide level is less than or equal to 110% of the lower limit of normal of the laboratory's measurement method; or
2. For beneficiaries with renal insufficiency and a creatinine clearance (actual or calculated from age, weight, and serum creatinine) less than or equal to 50 ml/minute, a fasting C-peptide level is less than or equal to 200% of the lower limit of normal of the laboratory’s measurement method; and
3. A fasting blood sugar obtained at the same time as the C-peptide level is less than or equal to 225 mg/dl; or
B. Beta cell autoantibody test is positive; and
C. The beneficiary has completed a comprehensive diabetes education program, has been on a program of multiple daily injections of insulin (i.e., at least 3 injections per day) with frequent self-adjustments of insulin dose for at least 6 months prior to initiation of the insulin pump, and has documented frequency of glucose self-testing an average of at least 4 times per day during the 2 months prior to initiation of the insulin pump, and meets one or more 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 hypoglycemia; or
   3. Wide fluctuations in blood glucose before mealtime; or
   4. Dawn phenomenon with fasting blood sugars frequently exceeding 200 mg/dL; or
   5. History of severe glycemic excursions; or

II. For non-pregnant, adult* patients 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:
   A. Non-Medicare members with type 2 diabetes.
   B. Type 1 diabetics not on insulin or taking only basal or bid insulin
   C. As a convenience item

Related Accessories and Supplies (Continued Coverage)

III. Continued coverage of related accessories and supplies for an external insulin pump requires that the beneficiary be seen and evaluated by the treating physician at least every 3 months.

Implantable Infusion Pump

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

Disposable Drug Delivery Systems

V. For non-Medicare members, disposable external insulin pumps with wireless communication capability to a hand-held control unit (e.g., OmniPod®) is acceptable alternative to a standard insulin infusion pump and considered medically necessary and is
**Diabetes: Insulin Infusion Pumps (External and Implanted)**

**Covered** if criterion I. above is met. Note: This criterion is only applicable to Medicare part B claims.

VI. For Medicare members only, **all disposable drug delivery systems**, (e.g., “patch pumps” including but not limited to OmniPod, V-Go, and Finesse) are considered **not medically necessary and are not covered**. Drugs and supplies used with disposable drug delivery systems are also non-covered items. Note: This criterion is only applicable to Medicare part B claims.

**Prior Pump Use in Medicare Members**

VII. Individuals with diabetes mellitus successfully using a continuous insulin infusion pump prior to enrollment, and have documented frequency of glucose self-testing on average of at least 4 times per day during the month prior to enrollment.

**Other Patient Populations**

The Providence Health Plan (PHP) CMS Medical Policy Manual (UM382) hierarchy of coverage indicates that in the absence of an NCD, LCD, LCA, or other coverage guideline, CMS allows coverage determinations to be based on an objective, evidenced-based process. Therefore, PHP commercial medical policy criteria may be applied to the following criteria: VIII.-XV.

**Pregnant Women and Children**

VIII. For children (17 years and younger) with type 1 diabetes or pregnant women with pre-gestational type 1 or type 2 diabetes an external infusion pump and related accessories, supplies, and insulin for administration of continuous subcutaneous insulin may be considered **medically necessary and covered** if criterion I. C. above is met. This includes disposable external insulin pumps with wireless communication capability to a hand-held control unit (e.g., OmniPod®).

NOTE: The 6 month period of frequent self-adjustments of insulin doses to initiate an insulin pump in criterion I.C. may be waived for children (17 years and younger) or pregnant women.

IX. For children (17 years and younger) with type 1 diabetes or pregnant women with pre-gestational type 1 or type 2 diabetes the pump and related accessories, supplies, and insulin are considered **not medically necessary and are not covered** if criterion I. C. is not met.

X. For non-pregnant women and children with type 2 diabetes or pregnant women with gestational diabetes the pump and related accessories, supplies, and insulin are considered **experimental/investigational and are not covered**.

**Enhancements/Optional Accessories**

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

Upgrade/Replacement of External Insulin Pumps

XII. Upgrade or replacement of an external insulin pump may be considered medically necessary and covered for children (age 17 years and younger) who require a larger insulin reservoir, when documentation is provided which includes the current insulin pump reservoir volume and the child’s current insulin needs.

XIII. Upgrade or replacement of an existing external insulin pump may be considered medically necessary and covered for adults and children when both of the following criteria (A.-B.) are met:

A. Documentation that one or more 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; and

B. Evidence of an evaluation by the health care provider managing the diabetes within the last six months that includes a recommendation supporting continued use of an external insulin pump.

XIV. Upgrade or replacement of an existing external insulin pump is considered not medically necessary and not covered when criteria (XII. or XIII.) above are not met.

XV. Upgrade or replacement of an existing functional external insulin pump for convenience or aesthetic purposes (e.g., wireless communication component) is considered cosmetic and is not covered.

BILLING GUIDELINES

Based on CPT code descriptions, a limit has been placed on the following code:

- A cumulative total of 52 units for supplies for maintenance of insulin infusion catheter (CPT: A4224) are eligible for reimbursement per calendar year.

Please see Coding Guidelines below for additional information on these codes.
KX, GA, GY and GZ MODIFIERS:

For all claims for external insulin infusion pumps (E0784) and insulin (J1817), if the results of the beneficiary's C-peptide level or beta cell autoantibody test meet the requirements outlined in section IV of the Coverage and Payment Rules in the related LCD, a KX modifier should be added to the HCPCS code.

In the situation above describing use of the KX modifier, if all of the coverage criteria have not been met, the GA or GZ modifier must be added to the code. When there is an expectation of a medical necessity denial, suppliers must enter the GA modifier on the claim line if they have obtained a properly executed Advance Beneficiary Notice (ABN) or the GZ modifier if they have not obtained a valid ABN.

Claims lines billed for the above services without a KX, GA, or GZ modifier will be rejected as missing information.

An infusion drug not administered using a durable infusion pump must be billed using the appropriate HCPCS code plus the GY modifier.

Other Billing Guidelines:

When an infusion pump is covered, the drug necessitating the use of the pump and necessary supplies are also covered. When a pump has been purchased by the Medicare program, other insurer, the beneficiary, or the rental cap has been reached, the drug necessitating the use of the pump and supplies are covered as long as the coverage criteria for the pump are met.

Supplies for the maintenance for an insulin infusion pump (A4224) are covered during the period of covered use of an infusion pump. They are also covered for the weeks in between covered infusion pump use, not to exceed 4 weeks per episode. Code A4224 may not be billed more than 52 times per calendar year.

Supplies used with an external infusion pump, A4222 and K0552 or supplies used with an insulin infusion pump (A4225) are covered during the period of covered use of an infusion pump. Allowance is based on the number of cassettes or bags (A4222) prepared or syringes (A4225, K0552) used. For intermittent infusions, no more than one cassette or bag is covered for each dose of drug. For continuous infusion, the concentration of the drug and the size of the cassette, bag, or syringe should be maximized to result in the fewest cassettes, bags, or syringes in keeping with good pharmacologic and medical practice.

Claims for codes A4221, A4222 and K0552 must only be used with a non-insulin external infusion pump (E0779, E0780, E0781, E0791 or K0455). Claims with dates of service on or after January 01, 2017 for codes A4221, A4222 and K0552 used with an external infusion pump HCPCS code E0784 are incorrectly coded.

Code A4224 describes all necessary supplies (excluding the insulin reservoir – see code A4225) used with an external infusion pump (E0784) for the administration of continuous subcutaneous insulin and includes, but is not limited to, all cannulas, needles, dressings and infusion supplies.
Code A4225 describes a syringe-type reservoir that is used with the external insulin infusion pump (E0784).

Claims for codes A4224 and A4225 must only be used with insulin infusion pumps (E0784). Claims with dates of service on or after January 01, 2017 for codes A4224 and A4225 used with an external infusion pump other than code E0784 are incorrectly coded.

Codes A4230 (infusion set for external insulin pump, non-needle cannulas type) and A4231 (infusion set for external insulin pump, needle type) are not valid for claim submission to the DME MAC because they are included in code A4224.

Use A4223 for infusion supplies not used with a covered external infusion pump. Use code J1817 for insulin administered through an external INSULIN PUMP (E0784).

Codes A4602, K0604 and K0605 describe lithium batteries commonly used in external infusion pumps. Note that each code has an associated voltage. Claims for lithium batteries for external insulin infusion pumps (E0784) that do not use a voltage described by either code A4602, K0604 and K0605 must be billed using code A9999.

Replacement batteries (K0601-K0605) are not separately payable when billed with a rented infusion pump.

**Guidelines for Non-Covered Services**

An infusion controller device (E1399) is not reasonable and necessary.

An IV pole (E0776) is considered not reasonable and necessary if it is billed with an ambulatory infusion pump (E0784).

A disposable drug delivery system (A4305, A4306, A9274) is a device used to deliver solutions containing injectable drugs that is not reusable, i.e., it is used by a single beneficiary for a limited time and then discarded.

Disposable drug delivery systems, including elastomeric infusion pumps (A4305, A4306, A9274) are non-covered devices because they do not meet the Medicare definition of durable medical equipment. Drugs and supplies used with disposable drug delivery systems are also non-covered items.

Catheter insertion devices for use with external insulin infusion pump infusion cannulas are included in the allowance for code A4224 and are not separately payable.

The DME MACs do not process claims for implantable infusion pumps (E0782, E0783, E0785, and E0786) or drugs and supplies used in conjunction with an implantable infusion pump. Claims for these items must be submitted to the A/B MAC.
### CPT/HCPCS Codes

**All Lines of Business**

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>E0784</td>
<td>External ambulatory infusion pump, insulin</td>
</tr>
<tr>
<td><strong>Prior Authorization Required</strong></td>
<td></td>
</tr>
<tr>
<td>A4224</td>
<td>Supplies for maintenance of insulin infusion catheter, per week</td>
</tr>
<tr>
<td>A4225</td>
<td>Supplies for external insulin infusion pump, syringe type cartridge, sterile, each</td>
</tr>
<tr>
<td>A4230</td>
<td>Infusion set for external insulin pump, non needle cannula type</td>
</tr>
<tr>
<td>A4231</td>
<td>Infusion set for external insulin pump, needle type</td>
</tr>
<tr>
<td>A4232</td>
<td>Syringe with needle for external insulin pump, sterile, 3 cc</td>
</tr>
<tr>
<td>J1817</td>
<td>Insulin for administration through DME (i.e., insulin pump) per 50 units</td>
</tr>
<tr>
<td>K0601</td>
<td>Replacement battery for external infusion pump owned by patient, silver oxide, 1.5 volt, each</td>
</tr>
<tr>
<td>K0602</td>
<td>Replacement battery for external infusion pump owned by patient, silver oxide, 3 volt, each</td>
</tr>
<tr>
<td>K0603</td>
<td>Replacement battery for external infusion pump owned by patient, alkaline, 1.5 volt, each</td>
</tr>
<tr>
<td>K0604</td>
<td>Replacement battery for external infusion pump owned by patient, lithium, 3.6 volt, each</td>
</tr>
<tr>
<td>K0605</td>
<td>Replacement battery for external infusion pump owned by patient, lithium, 4.5 volt, each</td>
</tr>
</tbody>
</table>

**Unlisted Codes**

All unlisted codes will be reviewed for medical necessity, correct coding, and pricing at the claim level. If an unlisted code is billed related to services addressed in this policy then prior-authorization is required.

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>E1399</td>
<td>Durable medical equipment, miscellaneous</td>
</tr>
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</table>

**All Lines of Business Except Medicare**

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
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<tr>
<td><strong>Prior Authorization Required</strong></td>
<td></td>
</tr>
<tr>
<td>A9274</td>
<td>External ambulatory insulin delivery system, disposable, each, includes all supplies and accessories</td>
</tr>
</tbody>
</table>

**Medicare only**

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Not Covered</strong></td>
<td></td>
</tr>
<tr>
<td>A9274</td>
<td>External ambulatory insulin delivery system, disposable, each, includes all supplies and accessories</td>
</tr>
</tbody>
</table>
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

Coverage determinations for non-CMS members may be based on an objective evidence-based process. Therefore, the evidence regarding the use of insulin pumps for non-CMS members is described below.

**Type 2 Diabetes Patients**

**Systematic Reviews**

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.\(^5\)

**Randomized Controlled Trials (RCTs)**

Since the reviews described above, only one RCT was identified, which is described below. 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.\(^6\) 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.

Twelve-month data was also published on the trial in 2016.\(^7\) 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**

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

The 2015 NICE guideline, “Type 2 Diabetes in Adults: Management”\(^8\), 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,\(^9\) recommended against the use of insulin pumps for treatment of type 2 diabetic patients of any age.

**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\(^10\) 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”\(^11\), regarding children under the age of 18, recommended criteria based on the 2008 Tech Appraisal Guidance [TA151].\(^9\) 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
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

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 (CSII; 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 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**

Providence Health Plan (PHP) and Providence Health Assurance (PHA) Medical Policies serve as guidance for the administration of plan benefits. Medical policies do not constitute medical advice nor a guarantee of coverage. PHP and PHA 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. PHP and PHA reserve the right to determine the application of Medical Policies and make revisions to its 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 PHP and PHA 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: Artificial Pancreas Devices and Other Integrated Systems (All Lines of Business Except Medicare), DME112
- Diabetes: Artificial Pancreas Devices and Other Integrated Systems (Medicare Only), DME397
- 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**


