Continuous Subcutaneous Insulin Infusion (CSII)

Disclaimer:
Please note that Baptist Health Plan Coverage Guidelines may be updated throughout the year. A printed version may not be most up to date version available. The health plan reserves the right to review and update this policy as needed. Refer to the website to ascertain that you are utilizing the most current available version. Clinical guideline policies are not intended to serve as treatment guidelines or treatment recommendation. Treating providers must use their own clinical judgment in rendering care to their patient population.

DEFINITION

Continuous subcutaneous insulin infusion (CSII) involves the use of an electronic insulin delivery system, or an insulin pump, in order to infuse insulin at a customizable and pre-programmed rate. For patients with Diabetes types I and II, the maintenance of stable glucose levels as a result of insulin therapy has been demonstrated to prevent many of the common acute metabolic complications often associated with the disease as well as delaying the onset and progression of macrovascular and microvascular complications. Although the use of CSII devices still require frequent blood glucose monitoring, insulin pumps eliminate the need for multiple daily injections (MDIs). Through computer programmed insulin delivery, both internal and external insulin pumps help maintain stable blood glucose levels often within normal ranges.¹

COVERAGE CRITERIA

Continuous subcutaneous insulin infusion (CSII) devices are considered durable medical equipment (DME) and as such must meet criteria in the Baptist Health Plan Certificate of Coverage regarding DME which includes but is not limited to the following:

- “If more than one piece of DME can meet your functional needs, benefits are available only for the most cost effective piece of equipment”
- “Replacement of DME may only be considered when the equipment to be replaced can no longer be made serviceable.”

Replacement of any insulin pump requires review by Baptist Health Plan including the following:
- Replacement of devices obtained prior to enrollment with Baptist Health Plan
• Replacement of devices no longer under warranty
• Replacement of devices that are not functioning properly and cannot be repaired
• Replacement of a device for a member who requires a larger insulin reservoir

CSII devices are medically necessary for adult members with diabetes as part of a comprehensive diabetes self-management plan who have not achieved optimal glycemic control who meet **ALL** the following criteria:

• Completion of a comprehensive diabetes education program with specific CSII training including the following:
  o Daily contact with a pump-trainer during therapy initiation; **and**
  o A return visit with the member’s medical providers within 3 to 7 days of initiation, after which continued visits should be made monthly during the pump stabilization phase and continued every three-months indefinitely; **and**
  o Continued educational consults on a weekly or biweekly basis as needed.

• Fully compliant with self-management of diabetes care as evident by both of the following:
  o Consistent insulin therapy as documented by the use of an external insulin pump or 4 insulin injections per day with frequent self-adjustments of the dose for at least 6-months; **and**
  o Documentation of self-testing of glucose level results at least 4 times a day for the past 2 months;

• Evidence of inadequate glycemic control as defined by the presence of **any** of the following:
  ▪ A glycated hemoglobin level (HbA1c) greater than 7.0%; **or**
  ▪ Documented episodes of hypoglycemia per medical record; **or**
  ▪ Fasting blood glucose levels frequently exceeding 200 mg/dL characteristic of dawn syndrome; **or**
  ▪ A history of severe glycemic excursions.  

Pregnant women with type 2 diabetes or gestational diabetes may also be eligible following the completion of a comprehensive diabetes education program including specific CSII training. Eligibility during pregnancy would include members that are at increased risk of maternal and fetal complications as evidenced by difficulty in glycemic control or the requirement of large doses of insulin.

CSII devices may be medically necessary for pediatric members over the age of 2 years and adolescent members with diabetes as part of a comprehensive diabetes self-management plan who have not achieved optimal glycemic control who meet ALL the following criteria:

• Completion of a comprehensive diabetes education program by member and guardian with specific CSII training including the following:
  ▪ Daily contact with a pump-trainer during therapy initiation; **and**
  ▪ A return visit with the member’s medical providers within 3 to 7 days of initiation, after which continued visits should be made monthly during the pump stabilization phase and continued every 3 months indefinitely; **and**
  ▪ Continued educational consults on a weekly or biweekly basis as needed.
• Fully compliant with self-management of diabetes care as evident by both of the following:
  ▪ Consistent insulin therapy as documented by the use of an external insulin pump or 4 insulin injections per day with frequent self-adjustments of the dose for at least 6 months; and
  ▪ Documentation of self-testing of blood glucose level results at least 4 times a day for the past 2 months; and

• Evidence of inadequate glycemic control as defined by the presence of any of the following:
  ▪ A glycated hemoglobin level (HbA1c) greater than 7.0%6 7 8
  ▪ Hypoglycemia as defined by a blood glucose level of less than 63 mg/dL (3.5 mmol/L) and the risk of injury or complication secondary to hypoglycemic episodes due to the presence of harmful symptoms. Characteristic symptoms of hypoglycemia are classified as neurogenic and neuroglycopenic symptoms, which may include but are not limited to tremor, palpitations, anxiety/arousal, sweating, paresthesia, cognitive impairment, behavioral changes, psychomotor abnormalities, seizure, and coma.9
  ▪ Fasting blood glucose levels frequently exceeding 200 mg/dL characteristic of dawn syndrome
  ▪ A history of severe glycemic excursions
  ▪ Microvascular complications and/or risk factors for macrovascular complications10 11 12

CSII devices are contraindicated for members meeting any of the following criteria:
  ▪ Medical, psychological or psychiatric disorders that prevent careful monitoring of glucose levels and overall compliance with diabetes self-care.13 14
  ▪ History of hypoglycemic unawareness.
  ▪ Concomitant medication that would interfere with insulin therapy.
  ▪ Inadequate body size to support the bulk of the pump in the subcutaneous tissues15
  ▪ Children under two years of age due to concerns regarding the adverse effect of hypoglycemia on brain development in very young children.

MEDICAL BACKGROUND

Continuous subcutaneous insulin infusion (CSII) devices administer an infusion of insulin at both a basal rate and a bolus rate. The basal rate is continuous and is intended to control baseline glucose levels between meals and during the night. The bolus rate infuses additional insulin in order to control glucose levels during mealtime or to correct acute glycemic episodes. This method of insulin delivery replaces the need for multiple daily injections (MDIs), but continuous glucose level monitoring is still necessary. In fact, given the continuous nature of CSII therapy, more frequent glucose monitoring is sometimes necessary.16

Peer-reviewed medical evidence is consistent across many studies proving that blood glucose level control reduces the risk of acute metabolic episodes as well as undermining the onset and progression of macrovascular and microvascular complications for people with diabetes mellitus.

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Glycemic control has also been shown to reduce many other common side effects of DM such as hypoglycemia and weight gain. For those who have not achieved optimal glycemic control with multiple daily insulin injections, the use of CSII devices may exist as an option for DM disease management.

A report compiled by the Agency for Healthcare Research and Quality (AHRQ) included results of a large inquiry into insulin delivery methods and blood glucose monitoring in July, 2012. This report also included a META-analysis of 44 publications including both randomized clinical trials and prospective studies. Different insulin delivery methods were evaluated across the studies with Hemoglobin A1C levels as the outcome variable. This report found that Hemoglobin A1C levels were comparable for those using CSII devices versus multiple daily injections (MDIs) for children and adolescents with type I DM and for adults with type II DM. However, adults with type I DM did demonstrate better Hemoglobin A1C levels with CSII. Also, this report demonstrated an improvement in quality of life as a result of CSII for those with type I DM, however, data for type II was insufficient to measure quality of life changes.

These results were consistent with a study published later the same year in which 33 randomized control trials were evaluated comparing CSII and MDI. Yeh and fellow researchers found that the outcomes were similar on glycemic control and hypoglycemia with the exception adults with type I DM, who demonstrated a superior outcome with the use of CSII devices over MDI.

These studies represent an update to the 2011 Hayes report of implantable insulin pumps in which studies evaluating implanted CSII devices were evaluated between the years 1992 through 2011. The studies evaluated the use of CSII for subjects with DM types I and II. Although the majority of these studies were relatively small, and since this report technology has improved dramatically, CSII use was given a proven rating for subjects with both types of DM who have experienced approved failures with MDI (MDI approved failures are those treatment failures necessary for approval of the pump by Baptist Health Plan which are listed in the Coverage Criteria). Also, CSII use was associated with a decrease in DM disease progression and complication outcomes such as diabetic retinopathy, neuropathy, and nephropathy. An updated 2015 Hayes Medical Technology report noted no new evidence since its last review that would modify the rating for this technology.

In 2014, practice guidelines published following a joint review by the American Association of Clinical Endocrinologists (AACE) and the American College of Endocrinology (ACE) emphasized the importance of appropriate patient selection criteria and its impact on clinical outcomes for CSII. The AACE/ACE defined ideal candidates as patients with both disease characteristics particularly difficult to control including labile diabetes, documented fluctuations in blood sugars characteristic of dawn syndrome as well as frequent episodes of hypoglycemia, elevated HbA1c and disease complications including microvascular complications in pediatric populations. The guidelines also noted the safety and efficacy of CSII in select pregnant women with diabetes type 1 or gestational diabetes. Additionally, the AACE/ACE emphasized the importance of patient compliance in self-management as evident by self-testing and multiple insulin injections. The relationship between clinical outcomes for CSII and nonmedical factors are well described.

In addition to meeting appropriate medical criteria for CSII, patients eligible for insulin pumps must be willing to engage in a collaborative relationship with their provider. Also, patients must demonstrate the ability and willingness to assume an active role in the management of their diseases as well as their device, learning advanced operation and maintenance techniques. Healthcare providers should be just as mindful of these nonmedical factors as they are of the medical aspects of CSII therapy when considering candidates for CSII devices.
REGULATORY INFORMATION

No legislative mandates were found for coverage of continuous subcutaneous insulin infusion pumps in Kentucky or Indiana.  

Baptist Health Plan Coverage Guidelines are created to provide members and providers with peer-reviewed, current medical information.

State and federal laws/mandates and contract language have priority over Coverage Guidelines and must be taken into consideration before eligibility for coverage is determined.

Baptist Health Plan Coverage Guidelines may or may not mirror Centers for Medicare & Medicaid Services benefits or coverage offered by any other health insurance company.

For self-funded plans, consult individual plan documents. If there is a conflict between this policy and a self-funded plan document, the provisions of the plan document will govern. In addition, coverage for Medicare Advantage members may differ. This is a result of applicable coverage statements by the Center for Medicare and Medicaid Services (CMS). The National Coverage Determinations, Local Coverage Determinations, and Local Medical Review Policies may be found at the CMS website, http://www.cms.gov. Please note that for all plans, the member’s health plan benefits that are in effect on the rendered date of service must be used in coverage determinations.

COVERAGE DETAIL

CODES INCLUDE BUT MAY NOT BE LIMITED TO THE FOLLOWING:

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<tr>
<th>CPT® Codes</th>
<th>Description</th>
<th>Coverage Information</th>
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<td></td>
<td>No specific code identified</td>
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<tr>
<th>HCPCS® Codes</th>
<th>Description</th>
<th>Coverage Information</th>
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<tbody>
<tr>
<td>A4221</td>
<td>Supplies for maintenance of drug infusion catheter, per week (includes infusion sets)</td>
<td>Is medically necessary when criteria are met</td>
</tr>
<tr>
<td>A4230</td>
<td>Infusion set for external insulin pump, non-needle cannula type</td>
<td>Is medically necessary when criteria are met</td>
</tr>
<tr>
<td>A4231</td>
<td>Infusion set for external insulin pump, needle type</td>
<td>Is medically necessary when criteria are met</td>
</tr>
<tr>
<td>Code</td>
<td>Description</td>
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<td>-----------------------------------------------</td>
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<td>A4232</td>
<td>Syringe with needle for external insulin pump, sterile, 3 cc</td>
<td>Is medically necessary when criteria are met</td>
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<td>A9274</td>
<td>External ambulatory insulin delivery system, disposable, each, includes all supplies and accessories</td>
<td>Is medically necessary when criteria are met</td>
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<td>E0784</td>
<td>External ambulatory infusion pump, insulin</td>
<td>Is medically necessary when criteria are met</td>
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<td>E1340</td>
<td>Repair or nonroutine service for durable medical equipment requiring the skill of a technician, labor component, per 15 minutes</td>
<td>Is medically necessary when criteria are met</td>
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<td>G0108</td>
<td>Diabetes outpatient self-management training services, individual, per 30 minutes</td>
<td>Is medically necessary when criteria are met</td>
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<td>G0109</td>
<td>Diabetes self-management training service, group session (2 or more), per 30 minutes</td>
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<td>K0552</td>
<td>Supplies for external drug infusion pump, syringe type cartridge, (reservoir), sterile, each</td>
<td>Is medically necessary when criteria are met</td>
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<td>K0601</td>
<td>replacement battery for external infusion pump owned by patient, silver oxide, 1.5 volt, each</td>
<td>Is medically necessary when criteria are met</td>
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<td>K0603</td>
<td>Replacement battery for external infusion pump owned by patient, alkaline, 1.5 volt, each</td>
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<td>K0604</td>
<td>Replacement battery for external infusion pump owned by patient, lithium, 3.6 volt, each</td>
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<td>S9145</td>
<td>Insulin pump initiation, instruction in initial use of pump (pump not included)</td>
<td>Is medically necessary when criteria are met</td>
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**ICD-9® Diagnosis Codes**

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<td>250.00 – 250.93</td>
<td>Diabetes Mellitus</td>
<td>Is medically necessary when criteria are met</td>
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</table>

**REFERENCES**

Continuous Subcutaneous Insulin Infusion (CSII)
01/10/17; 09/19/13; 05/17/09; 12/06/07


18 Agency for Healthcare Research and Quality (AHRQ) web site. Methods for insulin delivery


**SEARCH TERMS**

Blood sugar
Diabetes
Endocrinology
Glucose
Hypoglycemia
Implant
Insulin
Pump