Corporate Medical Policy

Insulin Therapy, Chronic Intermittent Intravenous (CIIIT)

Description of Procedure or Service

Chronic intermittent intravenous insulin therapy (CIIIT) is a technique for delivering variable-dosage insulin to diabetic patients with the goal of improved long-term glycemic control. Through an unknown mechanism, CIIIT is postulated to induce insulin-dependent hepatic enzymes to suppress glucose production.

Insulin-mediated glucose homeostasis involves 3 primary functions that occur at 3 locations: (1) insulin secretion by the pancreas; (2) glucose uptake, primarily in the muscle, liver, gut, and fat; and (3) hepatic glucose production. In the fasting state, when insulin levels are low, most glucose uptake into cells is non-insulin-mediated. Glucose uptake is then balanced by the liver production of glucose. However, after a glucose challenge, insulin binds to specific receptors on the hepatocyte to suppress glucose production. Without this inhibition, marked hyperglycemia may result.

Diabetes is characterized by elevated blood glucose levels due to inadequate or absent insulin production (type 1 diabetes) or due to a state of increased hepatic glucose production, decreased peripheral glucose uptake, and decreased insulin secretion (type 2 diabetes).

Different classes of diabetic drug therapy target different aspects of glucose metabolism. Various insulin secretagogues (i.e., sulfonylureas) function by increasing the pancreatic secretion of insulin; thiazolidinediones (i.e., pioglitazone [Actos®] and rosiglitazone [Avandia®]) function in part by increasing glucose uptake in the peripheral (principally skeletal) tissues; and biguanides (i.e., metformin) function by decreasing hepatic glucose production. While patients with type 2 diabetes may be treated with various combinations of all 3 of the above classes of drugs, with or without additional insulin, patients with type 1 diabetes, who have no baseline insulin secretion, receive exogenous insulin therapy. Standard insulin management involves the use of subcutaneous injection to mimic a physiologic insulin profile. Intravenous insulin is used in the acute, inpatient setting for the management of hyperglycemic emergencies (i.e., diabetic ketoacidosis).

Chronic intermittent intravenous insulin therapy (CIIIT), also referred to as outpatient intravenous insulin therapy (OIVIT), pulsatile intravenous insulin therapy, hepatic activation, or metabolic activation, involves delivering insulin intravenously several hours in a pulsatile fashion using a specialized pump controlled by a computerized program that adjusts the dosages based on frequent blood glucose monitoring. CIIIT is principally designed to normalize the hepatic metabolism of glucose. Currently, no studies have been identified that have investigated the proposed mechanism of action of CIIIT in humans.

Any insulin infusion pump can be used for the purposes of CIIIT. Infusion pumps have received U.S. Food and Drug Administration (FDA) marketing clearance through a 510(k) process, as they
Insulin Therapy, Chronic Intermittent Intravenous (CIIIT)

are determined to be substantially equivalent to predicate devices for the delivery of intravenous medications.

This policy does not apply to use of intravenous insulin infusions in the inpatient setting (ie, for the treatment of diabetic ketoacidosis or diabetic hyperosmolar coma).

***Note: This Medical Policy is complex and technical. For questions concerning the technical language and/or specific clinical indications for its use, please consult your physician.

Policy

Chronic Intermittent Intravenous Insulin Therapy is considered investigational. BCBSNC does not provide coverage for investigational services or procedures.

Benefits Application

This medical policy relates only to the services or supplies described herein. Please refer to the Member's Benefit Booklet for availability of benefits. Member's benefits may vary according to benefit design; therefore member benefit language should be reviewed before applying the terms of this medical policy.

When Insulin Therapy, Chronic Intermittent Intravenous (CIIIT) is covered

Not applicable.

When Insulin Therapy, Chronic Intermittent Intravenous (CIIIT) is not covered

Chronic intermittent intravenous insulin therapy (CIIIT) is considered investigational. BCBSNC does not cover investigational services.

Policy Guidelines

For individuals who have type 1 diabetes who receive chronic intermittent intravenous insulin therapy (CIIIT), the evidence includes 2 randomized controlled trials (RCTs) and uncontrolled studies. Relevant outcomes are symptoms, change in disease status, and treatment-related morbidity. A limited number of uncontrolled studies have suggested that CIIIT might improve glycemic control. The 2 RCTs reported that CIIIT might moderate the progression of nephropathy or retinopathy. However, the published studies were small and reported improvements on intermediate outcomes only (ie, changes in laboratory values). The clinical significance of the differences reported in these studies is uncertain. Additionally, most published evidence appeared between 1993 and 2010 and, as a result, does not account for recent improvements in diabetes care. The evidence is insufficient to determine the effects of the technology on health outcomes.

Billing/Coding/Physician Documentation Information

This policy may apply to the following codes. Inclusion of a code in this section does not guarantee that it will be reimbursed. For further information on reimbursement guidelines, please see Administrative Policies on the Blue Cross Blue Shield of North Carolina web site at www.bcbsnc.com. They are listed in the Category Search on the Medical Policy search page.

Applicable codes: G9147
Insulin Therapy, Chronic Intermittent Intravenous (CIIIT)

There is no specific CPT code describing chronic intermittent intravenous insulin therapy (CIIIT). Multiple CPT codes and HCPCS J codes may be used to describe the various components of CIIIT. Some codes, such as the code for glucose testing, may be used more than once during a single session of CIIIT.

BCBSNC may request medical records for determination of medical necessity. When medical records are requested, letters of support and/or explanation are often useful, but are not sufficient documentation unless all specific information needed to make a medical necessity determination is included.

Scientific Background and Reference Sources


Specialty Matched Consultant Advisory Panel 7/2012


Insulin Therapy, Chronic Intermittent Intravenous (CIIIT)


Medical Director review

Policy Implementation/Update Information

<table>
<thead>
<tr>
<th>Date</th>
<th>Action</th>
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</thead>
<tbody>
<tr>
<td>5/2002</td>
<td>Original policy issued.</td>
</tr>
<tr>
<td>4/2004</td>
<td>Benefits Application and Billing/Coding sections updated for consistency.</td>
</tr>
<tr>
<td>7/10/06</td>
<td>Specialty Matched Consultant Advisory Panel review 5/18/2006. No changes to policy statement. Rationale added to &quot;Policy Guidelines&quot; section. References added. Active Archive, policy no longer scheduled for routine literature review. (btw)</td>
</tr>
<tr>
<td>4/27/10</td>
<td>Policy status changed from “Active Policy, no longer scheduled for routine literature review” to “Active”. Removed the Policy Number. Added the following statement to the “Description” section indicating: “*The infusion pump used is specially designed for the purposes of CIIT. The pump received U.S. Food and Drug Administration (FDA) marketing clearance through a 510(k) process.” New HCPCS code G9147 added to the “Coding/Billing” section. References added. (btw)</td>
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<tr>
<td>8/30/11</td>
<td>Description section updated. No change to policy statement. Specialty Matched Consultant Advisory Panel review 7/27/11. (adn)</td>
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<tr>
<td>8/7/12</td>
<td>Policy Guidelines updated. No change to policy statement. Specialty Matched Consultant Advisory Panel review 7/18/12. (sk)</td>
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Insulin Therapy, Chronic Intermittent Intravenous (CIIIT)

11/13/12 Reference added. Related policy removed. No change to policy statement. (sk)

7/30/13 Specialty Matched Consultant Advisory Panel review 7/17/13. No change to policy statement. (sk)

8/27/13 Reference added. No change to policy statement. (sk)

8/12/14 Specialty Matched Consultant Advisory Panel review 7/29/14. Reference added. No change to policy statement. (sk)


9/30/16 Specialty Matched Consultant Advisory Panel review meeting 7/27/2016. No change to policy. (an)


7/27/18 Description section updated. Specialty Matched Consultant Advisory Panel review 6/27/2018. No change to policy statement. (an)


Medical policy is not an authorization, certification, explanation of benefits or a contract. Benefits and eligibility are determined before medical guidelines and payment guidelines are applied. Benefits are determined by the group contract and subscriber certificate that is in effect at the time services are rendered. This document is solely provided for informational purposes only and is based on research of current medical literature and review of common medical practices in the treatment and diagnosis of disease. Medical practices and knowledge are constantly changing and BCBSNC reserves the right to review and revise its medical policies periodically.