Corporate Medical Policy

Insulin Therapy, Chronic Intermittent Intravenous (CIIIT)

File Name: insulin_therapy_chronic_intermittent_intravenous
Origination: 5/2002
Last Review: 6/2024

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 update, 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 (ie, 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 over 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 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*

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

BCBSA Medical Policy Reference Manual, 11/20/2001; 2.01.43

Specialty Matched Consultant Advisory Panel - 7/2002

BCBSA Medical Policy Reference Manual [Electronic Version]. 2.01.43, 4/29/2003.

Specialty Matched Consultant Advisory Panel - 6/2004

American Diabetes Association. Clinical practice recommendations 2006. Diabetes Care. 2006;29:S4-S40. Retrieved 3/29/06 from http://care.diabetesjournals.org/cgi/content/full/29/suppl_1/s3

American Association of Clinical Endocrinologists. Medical guidelines for the management of diabetes mellitus: the AACE system of intensive diabetes self-management - 2002 update. Endocr Pract. 8(suppl 1):40-65. Retrieved 3/29/06 from http://test.aace.com/clin/guidelines/diabetes_2002.pdf

Specialty Matched Consultant Advisory Panel - 5/2006

BCBSA Medical Policy Reference Manual [Electronic Version]. 2.01.43, 9/10/2009

American Diabetes Association (ADA). 2010 Standards of Medical Care in Diabetes. Diabetes Care January 2010 vol. 33 no. Supplement 1 S11-S61. Retrieved on August 5, 2010 from http://care.diabetesjournals.org/search?fulltext=2010+medical+guidelines&submit=yes

Specialty Matched Consultant Advisory Panel 8/2010

BCBSA Medical Policy Reference Manual [Electronic Version]. 2.01.43, 9/16/2010

BCBSA Medical Policy Reference Manual [Electronic Version]. 2.01.43, 8/11/11

Specialty Matched Consultant Advisory Panel 7/2012

BCBSA Medical Policy Reference Manual [Electronic Version]. 2.01.43, 8/9/12

Specialty Matched Consultant Advisory Panel - 7/2013

BCBSA Medical Policy Reference Manual [Electronic Version]. 2.01.43, 7/11/13

Specialty Matched Consultant Advisory Panel - 7/2014

BCBSA Medical Policy Reference Manual [Electronic Version]. 2.01.43, 7/10/14

Specialty Matched Consultant Advisory Panel - 7/2015

BCBSA Medical Policy Reference Manual [Electronic Version]. 2.01.43, 7/10/15

BCBSA Medical Policy Reference Manual [Electronic Version]. 2.01.43, 2/11/2016

BCBSA Medical Policy Reference Manual [Electronic Version]. 2.01.43, 2/9/2017

BCBSA Medical Policy Reference Manual [Electronic Version]. 2.01.43, 2/8/2018

Centers for Medicaid & Medicare Services. National Coverage Determination (NCD) for Outpatient Intravenous Insulin Treatment (40.7). 2009; https://www.cms.gov/medicare-coverage-database

BCBSA Medical Policy Reference Manual [Electronic Version]. 2.01.43, 2/14/2019

Specialty Matched Consultant Advisory Panel 6/2020

BCBSA Medical Policy Reference Manual [Electronic Version]. 2.01.43, 2/13/2020

BCBSA Medical Policy Reference Manual [Electronic Version]. 2.01.43, 2/11/2021

Specialty Matched Consultant Advisory Panel 6/2021

Medical Director review

Draznin B, Aroda VR, Bakris G, et al. 9. Pharmacologic Approaches to Glycemic Treatment: Standards of Medical Care in Diabetes-2022. Diabetes Care. Jan 01 2022; 45(Supplement_1): S125-S143. PMID 34964831

Centers for Medicaid & Medicare Services. National Coverage Determination (NCD) for Outpatient Intravenous Insulin Treatment (40.7). 2009; https://www.cms.gov/medicare-coverage-database/details/ncd-details.aspx?NCDId=334. Accessed January 4, 2022.

Specialty Matched Consultant Advisory Panel 6/2022

Medical Director review 6/2022

Specialty Matched Consultant Advisory Panel 6/2023

Medical Director review 6/2023

Specialty Matched Consultant Advisory Panel 6/2024

Medical Director review 6/2024

Policy Implementation/Update Information

5/2002	Original policy issued.
8/2002	Specialty Matched Consultant Advisory Panel review 7/1/2002. No changes.
4/2004	Benefits Application and Billing/Coding sections updated for consistency.
6/24/04	Specialty Matched Consultant Advisory Panel review. No changes to criteria. /References added.
7/10/06	Specialty Matched Consultant Advisory Panel review 5/18/2006. No changes to policy statement. Rationale added to “Policy Guidelines” section. References added. Active Archive, policy no longer scheduled for routine literature review. (btw)

4/27/10	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 CIIIT. 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)
9/28/10	Specialty Matched Consultant Advisory Panel review 8/2010. References updated. (mco)
8/30/11	Description section updated. No change to policy statement. Specialty Matched Consultant Advisory Panel review 7/27/11. (adn)
8/7/12	Policy Guidelines updated. No change to policy statement. Specialty Matched Consultant Advisory Panel review 7/18/12. (sk)
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)
9/1/15	Specialty Matched Consultant Advisory Panel review 7/29/15. Reference added. Description section and Policy Guidelines updated. (sk)
9/30/16	Specialty Matched Consultant Advisory Panel review meeting 7/27/2016. No change to policy. (an)
8/11/17	Updated Policy Guidelines. Reference added. Information added to Billing/Coding section. Specialty Matched Consultant Advisory Panel review meeting 7/26/17. No change to policy statement. (an)
7/27/18	Description section updated. Specialty Matched Consultant Advisory Panel review 6/27/2018. No change to policy statement. (an)
7/16/19	Policy Guidelines updated. References added. Specialty Matched Consultant Advisory Panel review meeting 6/19/2019. (eel)
7/14/20	References added. Description and Policy Guidelines updated. Specialty Matched Consultant Advisory Panel review 6/17/2020. (eel)
7/1/21	Policy Guidelines updated. References added. Specialty Matched Consultant Advisory Panel review 6/2021. (bb)
7/12/22	References added. Specialty Matched Consultant Advisory Panel review 6/2022. Medical Director review 6/2022. No changes to policy statement or intent. (tt)
6/30/23	References added. Specialty Matched Consultant Advisory Panel review 6/2023. Medical Director review 6/2023. No changes to policy statement or intent. (tt)
7/17/24	References added. Specialty Matched Consultant Advisory Panel review 6/2023. Medical Director review 6/2023. No changes to policy statement or intent. (tt)