Chronic Intermittent Intravenous Insulin Therapy (CIIIT)

Policy # 00015
Original Effective Date: 06/05/2002
Current Effective Date: 06/12/2023

Applies to all products administered or underwritten by Blue Cross and Blue Shield of Louisiana and its subsidiary, HMO Louisiana, Inc. (collectively referred to as the “Company”), unless otherwise provided in the applicable contract. Medical technology is constantly evolving, and we reserve the right to review and update Medical Policy periodically.

Services Are Considered Investigational
Coverage is not available for investigational medical treatments or procedures, drugs, devices or biological products.

Based on review of available data, the Company considers chronic intermittent intravenous insulin (CIIIT) therapy to be investigational.*

Policy Guidelines
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).

Background/Overview
Glucose Homeostasis
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.

Medications for Glucose Homeostasis in Diabetes
Diabetes is characterized by elevated blood glucose levels due to inadequate or absent insulin production (type 1 diabetes) or due to increased hepatic glucose production, decreased peripheral glucose uptake, and decreased insulin secretion (type 2 diabetes).

Patients with type 1 diabetes require insulin therapy. Insulin therapy for patients with type 1 diabetes usually consists of multiple daily subcutaneous injections with both basal and mealtime insulin or
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Continuous subcutaneous insulin infusions given through an insulin pump. Insulin therapy has improved over the last several decades with newer insulin products providing improved pharmacokinetic parameters to closer mimic physiologic insulin. Intravenous insulin is used in the acute inpatient setting to manage hyperglycemic emergencies (e.g., diabetic ketoacidosis).

FDA or Other Governmental Regulatory Approval

U.S. Food and Drug Administration (FDA)
Any insulin infusion pump can be used for chronic intermittent intravenous insulin therapy. Infusion pumps have been cleared for marketing by the U.S. Food and Drug Administration (FDA) through the 510(k) process. The FDA determined that this device was substantially equivalent to existing devices for the delivery of intravenous medications. FDA product code: lZG.

Rationale/Source

This medical policy was developed through consideration of peer-reviewed medical literature generally recognized by the relevant medical community, U.S. Food and Drug Administration approval status, nationally accepted standards of medical practice and accepted standards of medical practice in this community, technology evaluation centers, reference to federal regulations, other plan medical policies, and accredited national guidelines.

Chronic intermittent intravenous insulin therapy (CIIIT) is a technique for delivering variable-dose 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.

Summary of Evidence

For individuals who have type 1 diabetes who receive chronic intermittent intravenous insulin therapy (CIIIT), the evidence includes 2 randomized controlled trials (RCTs) and several 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 have reported that CIIIT might moderate the progression of nephropathy or retinopathy. However, the published studies were small and reported improvements on intermediate outcomes only (i.e., changes in laboratory values). The clinical significance of the differences reported in these trials is uncertain. Additionally, most published evidence appeared
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between 1993 and 2010 and, as a result, does not account for improvements in diabetes care. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

Supplemental Information
Practice Guidelines and Position Statements
Guidelines or position statements will be considered for inclusion in Supplemental Information if they were issued by, or jointly by, a U.S. professional society, an international society with US representation, or National Institute for Health and Care Excellence (NICE). Priority will be given to guidelines that are informed by a systematic review, include strength of evidence ratings, and include a description of management of conflict of interest.

American Diabetes Association
The 2022 American Diabetes Association “Standards of Medical Care in Diabetes” includes the American Diabetes Association’s current clinical practice recommendations and is intended to provide the components of diabetes care, general treatment goals and guidelines, and tools to evaluate the quality of care. There is no mention of chronic intermittent intravenous insulin therapy (CIIIT).

American Association of Clinical Endocrinology
In 2022, the American Association of Clinical Endocrinology updated its 2015 clinical practice guideline for developing a diabetes mellitus comprehensive care plan. The guideline includes evidence-based recommendations for the comprehensive care of people with both type 1 and type 2 diabetes; recommendations are divided up into 4 sections: screening, diagnosis, targets, and monitoring; comorbidities and complications; management; education and new topics regarding diabetes. There is no mention of CIIIT.

U.S. Preventive Services Task Force Recommendations
Not applicable.

Medicare National Coverage
The 2009 Centers for Medicare & Medicaid Services issued a decision memo on the use of outpatient intravenous insulin therapy, which stated:
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“Effective … 2009, the Centers for Medicare and Medicaid Services (CMS) determines that the evidence is adequate to conclude that OIVIT [outpatient intravenous insulin therapy] does not improve health outcomes in Medicare beneficiaries. Therefore, CMS determines that OIVIT is not reasonable and necessary…. Services comprising an Outpatient Intravenous Insulin Therapy regimen are nationally non-covered under Medicare when furnished pursuant to an OIVIT regimen….“

Ongoing and Unpublished Clinical Trials
A search for active or recruiting clinical trials in December 2022 did not yield results for trials that might influence this review.

References
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Policy History
Original Effective Date:  06/05/2002
Current Effective Date:  06/12/2023
04/18/2002  Medical Policy Committee review
06/05/2002  Managed Care Advisory Council approval
06/24/2002  Format revision. No substance change to policy
06/01/2004  Medical Director review
06/15/2004  Medical Policy Committee review. Format revision. No substance change to policy.
06/28/2005  Managed Care Advisory Council approval
03/01/2005  Medical Director review
03/15/2005  Medical Policy Committee review
04/04/2005  Managed Care Advisory Council approval
07/07/2006  Format revision, including addition of FDA and or other governmental regulatory approval and rationale/source. Coverage eligibility unchanged.
04/04/2007  Medical Director review
04/18/2007  Medical Policy Committee approval. CMS information added. Coverage eligibility unchanged.
03/04/2009  Medical Director review
03/18/2009  Medical Policy Committee approval. No change to coverage.
03/05/2010  Medical Policy Committee review
03/19/2010  Medical Policy Implementation Committee approval. No change to coverage.
03/03/2011  Medical Policy Committee review
03/16/2011  Medical Policy Implementation Committee approval. No change to coverage.
03/01/2012  Medical Policy Committee review
03/21/2012  Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
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03/07/2013 Medical Policy Committee review
03/20/2013 Medical Policy Implementation Committee approval. Coverage eligibility unchanged.

03/06/2014 Medical Policy Committee review
03/19/2014 Medical Policy Implementation Committee approval. Coverage eligibility unchanged.

05/07/2015 Medical Policy Committee review
05/20/2015 Medical Policy Implementation Committee approval. Coverage eligibility unchanged.

08/03/2015 Coding update: ICD10 Diagnosis code section added; ICD9 Procedure code section removed.

05/05/2016 Medical Policy Committee review
05/18/2016 Medical Policy Implementation Committee approval. Coverage eligibility unchanged.

10/01/2016 Coding update
01/01/2017 Coding update: Removing ICD-9 Diagnosis Codes

05/04/2017 Medical Policy Committee review
05/17/2017 Medical Policy Implementation Committee approval. Coverage eligibility unchanged.

05/03/2018 Medical Policy Committee review
05/16/2018 Medical Policy Implementation Committee approval. Coverage eligibility unchanged.

05/02/2019 Medical Policy Committee review
05/15/2019 Medical Policy Implementation Committee approval. Coverage eligibility unchanged.

05/07/2020 Medical Policy Committee review
05/13/2020 Medical Policy Implementation Committee approval. Coverage eligibility unchanged.

05/06/2021 Medical Policy Committee review
05/12/2021 Medical Policy Implementation Committee approval. Coverage eligibility unchanged.

05/05/2022 Medical Policy Committee review
05/11/2022 Medical Policy Implementation Committee approval. Coverage eligibility unchanged.

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12/20/2022 Coding update
05/04/2023 Medical Policy Committee review
05/10/2023 Medical Policy Implementation Committee approval. Coverage eligibility unchanged.

Next Scheduled Review Date: 05/2024

Coding
The five character codes included in the Blue Cross Blue Shield of Louisiana Medical Policy Coverage Guidelines are obtained from Current Procedural Terminology (CPT®), copyright 2022 by the American Medical Association (AMA). CPT is developed by the AMA as a listing of descriptive terms and five character identifying codes and modifiers for reporting medical services and procedures performed by physician.

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Codes used to identify services associated with this policy may include (but may not be limited to) the following:

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<th>Code Type</th>
<th>Code</th>
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<td>HCPCS</td>
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<td></td>
<td>Delete codes effective 01/01/2023: A9277, E0784</td>
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<tr>
<td>ICD-10 Diagnosis</td>
<td>All related diagnoses</td>
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*Investigational – A medical treatment, procedure, drug, device, or biological product is Investigational if the effectiveness has not been clearly tested and it has not been incorporated into standard medical practice. Any determination we make that a medical treatment, procedure, drug, device, or biological product is Investigational will be based on a consideration of the following:

A. Whether the medical treatment, procedure, drug, device, or biological product can be lawfully marketed without approval of the U.S. Food and Drug Administration (FDA) and whether such approval has been granted at the time the medical treatment, procedure, drug, device, or biological product is sought to be furnished; or

B. Whether the medical treatment, procedure, drug, device, or biological product requires further studies or clinical trials to determine its maximum tolerated dose, toxicity, safety, effectiveness, or effectiveness as compared with the standard means of treatment or diagnosis, must improve health outcomes, according to the consensus of opinion among experts as shown by reliable evidence, including:

1. Consultation with technology evaluation center(s);
2. Credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community; or
3. Reference to federal regulations.

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NOTICE: If the Patient’s health insurance contract contains language that differs from the BCBSLA Medical Policy definition noted above, the definition in the health insurance contract will be relied upon for specific coverage determinations.
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