



# Louisiana

## Chronic Intermittent Intravenous Insulin Therapy (CIIT)

**Policy #** 00015

**Original Effective Date:** 06/05/2002

**Current Effective Date:** 05/16/2018

*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 (CIIT) therapy to be **investigational**.\*

### **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).

The different classes of diabetic drug therapy target different aspects of glucose metabolism. Various insulin secretagogues (e.g., sulfonylureas) function by increasing the pancreatic secretion of insulin; thiazolidinediones (e.g., pioglitazone [Actos], rosiglitazone [Avandia]) function in part by increasing glucose uptake in the peripheral (principally skeletal) tissues; and biguanides (e.g., metformin) function by decreasing hepatic glucose production. While patients with type 2 diabetes may be treated with various combinations of all three of these 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 to manage hyperglycemic emergencies (e.g., diabetic ketoacidosis).

#### **Chronic Intermittent Insulin Therapy**

Several forms of chronic intermittent insulin therapy, in which insulin is delivered intravenously or into the peritoneal space, have been evaluated.

CIIT—also referred to as outpatient intravenous insulin therapy, pulsatile intravenous insulin therapy, hepatic activation therapy, or metabolic activation therapy—involves delivering insulin intravenously once

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weekly over several hours in a pulsatile fashion using a specialized pump controlled by a computerized program that adjusts the doses based on frequent blood glucose monitoring. CIIT 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 CIIT in humans.

Aoki et al (1993) proposed that, in patients with type 1 diabetes, lower levels of insulin in the portal vein are associated with a decreased concentration of the liver enzymes required for hepatic metabolism of glucose. They stated: "We reasoned that if the liver of an IDDM [insulin-dependent diabetes mellitus; i.e., type 1 diabetes] patient could be perfused with near-normal concentrations of insulin during meals, the organ could be reactivated," and proposed that intermittent intravenous pulsatile infusions of insulin administered once weekly while the patient ingests a carbohydrate meal would increase the portal vein concentrations of insulin, ultimately stimulating the synthesis of glucokinase and other insulin-dependent enzymes. The pulses are designed to deliver a higher, more physiologic concentration of insulin to the liver than is delivered by traditional subcutaneous injections. This higher level of insulin is thought to more closely mimic the body's natural levels of insulin because it is delivered to the liver. The goal of this outpatient therapy is improved glucose control through improved hepatic activation.

### **FDA or Other Governmental Regulatory Approval**

#### **U.S. Food and Drug Administration (FDA)**

Any insulin infusion pump can be used for CIIT. Infusion pumps have been cleared for marketing by the U.S. 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: IZG.

#### **Centers for Medicare and Medicaid Services (CMS)**

In 2009, the Centers for Medicare & Medicaid Services issued a decision memo on the use of outpatient intravenous insulin therapy, which stated:

"Effective ... 2009, the CMS determines that the evidence is adequate to conclude that OIVIT [outpatient intravenous insulin therapy; CIIT] does not improve health outcomes in Medicare beneficiaries. Therefore, CMS determines that OIVIT is not reasonable and necessary.... Services comprising an OIVIT regimen are nationally non-covered under Medicare when furnished pursuant to an OIVIT regimen...."

### **Rationale/Source**

Evidence reviews assess the clinical evidence to determine whether the use of a technology improves the net health outcome. Broadly defined, health outcomes are length of life, quality of life, and ability to function—including benefits and harms. Every clinical condition has specific outcomes that are important to patients and to managing the course of that condition. Validated outcome measures are necessary to ascertain whether a condition improves or worsens; and whether the magnitude of that change is clinically significant. The net health outcome is a balance of benefits and harms.

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To assess whether the evidence is sufficient to draw conclusions about the net health outcome of a technology, 2 domains are examined: the relevance and the quality and credibility. To be relevant, studies must represent one or more intended clinical use of the technology in the intended population and compare an effective and appropriate alternative at a comparable intensity. For some conditions, the alternative will be supportive care or surveillance. The quality and credibility of the evidence depend on study design and conduct, minimizing bias and confounding that can generate incorrect findings. The randomized controlled trial (RCT) is preferred to assess efficacy; however, in some circumstances, nonrandomized studies may be adequate. RCTs are rarely large enough or long enough to capture less common adverse events and long-term effects. Other types of studies can be used for these purposes and to assess generalizability to broader clinical populations and settings of clinical practice.

The following is a key summary of the literature to date, which primarily addresses whether CIIT improves glycemic control in diabetic patients and whether CIIT reduces end-organ damage associated with diabetes.

### **CIIT FOR TYPE 1 DIABETES**

#### **Glycemic Control**

Aoki et al (1993) published a case series of 20 patients with “brittle” type 1 diabetes. All patients received 4 daily injections of insulin (type of insulin not described); additional oral drug therapy, if any, was not described. Throughout the study, patients remained in close contact with the clinic (at least once a week), during which time appropriate adjustments in diet, insulin doses, and physical activity were made. While the study reported a decrease in the hemoglobin A<sub>1c</sub> (HbA<sub>1c</sub>) levels, the lack of a control group limits interpretation of the results. For example, the intense follow-up of the patients could have impacted results, regardless of any possible effects of the CIIT.

Aoki et al (1995) also examined the effect of CIIT with hypertensive medications in 26 patients with type 1 diabetes and associated hypertension and nephropathy. The 26 patients were randomized to a control group or a treatment group for 3 months and then crossed over for an additional 3 months. At baseline, all patients were being treated with 4 daily insulin injections and had achieved acceptable HbA<sub>1c</sub> levels of 7.4%. Patients also achieved acceptable baseline blood pressure control (<140/90 mm Hg) with a variety of medications (i.e., angiotensin-converting enzyme inhibitors, calcium channel blockers, loop diuretics, alpha-2 agonists). The study was randomized, but not blinded, in that sham CIIT procedures were not performed. Therefore, those patients receiving CIIT received more intense follow-up during this period. During the treatment phase, patients reported a significant decrease in dosage of antihypertensive medicines. No difference in glycemic control was noted. Because all patients had adequate blood pressure control at baseline, the clinical significance of the decrease in antihypertensive dosage requirement associated with CIIT is uncertain.

#### **Section Summary: Glycemic Control**

One nonblinded RCT and a cases series reporting on the effect of CIIT on glycemic control in type 1 diabetes were identified. Both studies reported improvements: one in HbA<sub>1c</sub> levels compared with baseline, and the other in a dose of antihypertensive medication in the treatment group compared with control.

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However, the lack of a blinded control comparator group in the RCT limits the conclusions that can be drawn.

### **Reductions in Diabetic End-Organ Damage**

Weinrauch et al (2010) published an RCT of the effects of CIIT on progression of nephropathy and retinopathy in 65 subjects with type 1 diabetes. Patients were randomized to standard therapy of 3 to 4 daily subcutaneous insulin injections (n=29; control group) or standard therapy plus weekly CIIT (n=36; treatment group). Baseline demographic characteristics were similar between the 2 groups, as were the age of onset, duration of diabetes, control of HbA<sub>1c</sub> levels, and renal function (average creatinine, 1.59 mg/dL; average creatinine clearance, 60.6 mL/min). Primary end points were a progression of diabetic retinopathy and nephropathy. There was no significant difference in progression of diabetic retinopathy. Progression was noted in 18.8% of 122 eyes adequately evaluated (17.9% of 67 treated eyes, 20.0% of 55 controls; p=0.39). On average, serum creatinine increased in both groups; the increase was smaller in the treatment group (0.09 mg/dL) than in the control group (0.39 mg/dL; p=0.035). While average creatinine clearance fell less in the treatment group (-5.1 mL/min), the difference vs standard therapy was not significant (-9.9 mL/min; p=0.30). Glycemic control did not vary significantly. The clinical significance of the difference in creatinine levels is uncertain.

Dailey et al (2000) reported on a prospective, multicenter, controlled study evaluating the effects of CIIT on the progression of diabetic nephropathy. They assessed 49 type 1 diabetes patients with nephropathy who were following the Diabetes Control and Complications Trial intensive therapy regimen. Of these, 26 were assigned to the control group, which continued intensive therapy, and 23 were assigned to the treatment group, which underwent weekly CIIT plus intensive therapy. Both groups reported a significant decrease in HbA<sub>1c</sub> levels during the 18-month study period. Creatinine clearance declined in both groups as expected, but the rate of decline in the treatment group was significantly less than in the control group. The clinical significance of this finding is uncertain. Larger clinical trials that evaluate the end point of time to progression of renal failure are needed.

### **Section Summary: Reductions in Diabetic End-Organ Damage**

Two controlled studies focusing on the efficacy of CIIT for reducing diabetic end-organ complications were identified. Both reported significant improvements in intermediate measures of glycemic control in each group from pre- to postintervention, but did not consistently report differences in clinically meaningful outcomes from the beginning of the studies to the end. Similarly, there were no significant differences between treatment groups in the RCT.

### **SUMMARY OF EVIDENCE**

For individuals who have type 1 diabetes who receive CIIT, the evidence includes 2 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 CIIT might improve glycemic control. The 2 randomized trials have reported that CIIT 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

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these trials is uncertain. Additionally, most published evidence appeared between 1993 and 2000 and, as a result, does not account for improvements in diabetes care. The evidence is insufficient to determine the effects of the technology on health outcomes.

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### Policy History

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|------------|--|
| 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   |

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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.
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.
Next Scheduled Review Date:	05/2019

### **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)<sup>®†</sup>, copyright 2017 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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*CPT is a registered trademark of the American Medical Association.*

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

Code Type	Code
CPT	No codes
HCPCS	A9277, E0784, G9147, J1817
ICD-10 Diagnosis	E08.3211-E08.3219      E08.3291-E08.3299      E08.3311-E08.3319      E08.3391-E08.3399
	E08.3411-E08.3419      E08.3491-E08.3499      E08.3511-E08.3519      E08.3521-E08.3529
	E08.3531-E08.3539      E08.3541-E08.3549      E08.3551-E08.3559      E08.3591-E08.3599
	E08.37X1-E08.37X9      E09.3211-E09.3219      E09.3291-E09.3299      E09.3311-E09.3399
	E09.3411-E09.3419      E09.3491-E09.3499      E09.3511-E09.3519      E09.3521-E09.3529
	E09.3531-E09.3539      E09.3541-E09.3549      E09.3551-E09.3559      E09.3591-E09.3599
	E09.37X1-E09.37X9      E10.10-E10.11      E10.311-E10.352      E10.3211-E10.3219
	E10.3291-E10.3299      E10.3311-E10.3319      E10.3391-E10.3399      E10.3411-E10.3419
	E10.3491-E10.3499      E10.3511-E10.3519      E10.3521-E10.3529      E10.3531-E10.3539
	E10.3541-E10.3549      E10.3551-E10.3559      E10.3591-E10.3599      E10.36-E10.59
	E10.37X1-E10.37X9      E10.610-E10.69      E10.8-E10.9      E11.00-E11.359
	E11.3211-E11.3219      E11.3291-E11.3299      E11.3311-E11.3319      E11.3391-E11.3399
	E11.3411-E11.3499      E11.3511-E11.3599      E11.37X1-E11.37X9      E13.3211-E13.3219
	E13.3291-E13.3299      E13.3311-E13.3399      E13.3411-E13.3419      E13.3491-E13.3499
	E13.3511-E13.3519      E13.3521-E13.3529      E13.3531-E13.3539      E13.3541-E13.3549
	E13.3551-E13.3559      E13.3591-E13.3599      E11.36-E11.9      E13.00-E13.9

\*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 the Blue Cross and Blue Shield Association technology assessment program (TEC) or other nonaffiliated 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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