

**WellCare Health Plans, Inc.**  
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# *Clinical Coverage Guideline*



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## **Chronic Intermittent Intravenous Insulin Therapy (CIIT) for Type 1 Diabetes Mellitus**

**Guideline Number: HS-085**

**Original Effective Date: 2/16/2009**

**Revision Date: 2/26/2010**

The Clinical Coverage Guideline is intended to supplement certain standard WellCare benefit plans. The terms of a member's particular Benefit Plan, Evidence of Coverage, Certificate of Coverage, etc., may differ significantly from this Coverage Position. For example, a member's benefit plan may contain specific exclusions related to the topic addressed in this Clinical Coverage Guideline. When a conflict exists between the two documents, the Member's Benefit Plan always supersedes the information contained in the Clinical Coverage Guideline. Additionally, Clinical Coverage Guidelines relate exclusively to the administration of health benefit plans and are NOT recommendations for treatment, nor should they be used as treatment guidelines. The application of the Clinical Coverage Guideline is subject to the benefit determinations set forth by the Centers for Medicare and Medicaid Services (CMS) National and Local Coverage Determinations and state-specific Medicaid mandates, if any.

# Clinical Coverage Guideline HS-085

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### DISCLAIMER

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### APPLICATION STATEMENT

The application of the Clinical Coverage Guideline is subject to the benefit determinations set forth by the Centers for Medicare and Medicaid Services (CMS) National and Local Coverage Determinations and state-specific Medicaid mandates, if any.

### CLINICAL COVERAGE GUIDELINE

**Chronic intermittent intravenous insulin therapy (CIIT, also known as hepatic activation therapy, metabolic activation therapy, or pulsatile intravenous insulin therapy [PIVIT]) is considered experimental and investigational and NOT a covered benefit for the management of diabetes mellitus and all other indications. The clinical value of the procedure has not been established.**

### BACKGROUND

Hepatic activation, also referred to as chronic intermittent intravenous insulin infusion therapy (CIIT) or pulsatile IV insulin therapy (PIVIT), is a treatment for diabetes, involving the delivery of insulin intravenously over a six to seven hour period in a pulsatile fashion, using a specialized pump controlled by a computerized program. The dosages of insulin are adjusted, based on frequent blood glucose monitoring, and are designed to deliver a higher, more physiologic concentration of insulin to the liver than is delivered by traditional subcutaneous injections of insulin. It is hoped that this therapy ultimately results in improved glucose control through improved hepatic activation. Although the exact physiologic mechanism is unclear, Aoki (1993), one of the principal investigators of CIIT, proposes that, in diabetics, lower levels of insulin in the portal vein are associated with a decreased concentration of the liver enzymes required for hepatic metabolism of glucose. Once weekly, 6-hour intravenous pulsatile infusions of insulin while the patient ingests a carbohydrate meal are designed to increase the portal vein concentrations of insulin, ultimately stimulating the synthesis of glucokinase and other insulin-dependent enzymes.

#### *Professional Statements*

Professional statements from several specialty societies on the management of patients with diabetes mellitus, listed below, did not discuss the use of CIIT.

- The American Association of Clinical Endocrinologists/American College of Endocrinology's guideline for the

management of DM (2002).

- The National Collaborating Center for Chronic Conditions' clinical guideline on the diagnosis and management of adults with type 1 DM (2004).
- The American Diabetes Association (ADA)'s position statement on care of children and adolescents with type 1 DM (Silverstein et al, 2005).
- The ADA's position statement on nutrition recommendations and interventions for DM (ADA, 2007).

#### *Hayes Statement*

“There is insufficient evidence from the limited number of published studies to conclude that CIIT is effective in reducing symptoms, improving glycemic control, or preventing diabetic sequelae in patients with type 1 diabetes. Although results of several of the studies suggest that CIIT may improve glycemic control, facilitate blood pressure control, and/or slow progression of nephropathy, the lack of adequate controls, randomization, and blinding, and the small sample sizes of the available studies preclude definitive conclusions regarding the health benefit of CIIT. Double-blind RCTs of adequate size are necessary to evaluate this therapy adequately. A Hayes rating of C is given” (from Hayes, 2006).

#### **CODING**

**CIIT is considered experimental and investigational and NOT a covered benefit** for the management of diabetes mellitus and all other indications.

#### **CPT® Codes**

No applicable codes

#### **ICD-9-CM Procedure Codes**

No applicable codes

#### **Non-Covered HCPCS Codes**

J1815 Injection, insulin, per 5 units

J1817 Insulin for administration through DME (i.e. insulin pump) per 50 units

#### **Non-Covered ICD-9-CM Diagnosis Codes**

250.00 - 250.93 Diabetes mellitus

648.00 - 648.04 Diabetes mellitus complicating pregnancy, childbirth, or the puerperium

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