



**CHRONIC INTERMITTENT INTRAVANEIOUS INSULIN
THERAPY (CIIT) FOR TYPE 1 DIABETES MELLITUS
HS-085**



Harmony Behavioral Health, Inc.

Harmony Behavioral Health of Florida, Inc.

Harmony Health Plan of Illinois, Inc.

HealthEase of Florida, Inc.

*'Ohana Health Plan, a plan offered by
WellCare Health Insurance of Arizona, Inc.*

WellCare Health Insurance of Illinois, Inc.

WellCare Health Insurance of New York, Inc.

WellCare Health Plans of New Jersey, Inc.

WellCare of Florida, Inc.

WellCare of Connecticut, Inc.

WellCare of Georgia, Inc.

WellCare of Kentucky, Inc.

WellCare of Louisiana, Inc.

WellCare of New York, Inc.

WellCare of Ohio, Inc.

WellCare of Texas, Inc.

WellCare Prescription Insurance, Inc.

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

Policy Number: HS-085

Original Effective Date: 2/16/2009

Revised Date(s): 2/26/2010; 2/26/2011

DISCLAIMER

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.

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.

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).

POSITION STATEMENT

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.

CODING

CPT® Codes - No applicable codes

ICD-9-CM Procedure Codes - No applicable codes

Clinical Coverage Guideline

page 2



CHRONIC INTERMITTENT INTRAVANEIOUS INSULIN THERAPY (CIIT) FOR TYPE 1 DIABETES MELLITUS HS-085

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

*Current Procedural Terminology (CPT®) ©2010 American Medical Association: Chicago, IL

REFERENCES

Peer Reviewed

1. Aoki TT, Grecu EO, Arcangeli MA, et al. Chronic intermittent intravenous insulin therapy: a new frontier in diabetes therapy. *Diabetes Technol Ther.* 2001; 3(1):111-123.
2. Aoki TT, Grecu EO, Arcangeli MA. Chronic intermittent intravenous insulin therapy corrects orthostatic hypotension of diabetes. *Amer J Med.* 1995; 99(6):683-684.
3. Aoki TT, Grecu EO, Prendergast JJ, et al. Effect of chronic intermittent intravenous insulin therapy on antihypertensive medication requirement in IDDM subjects with hypertension and nephropathy. *Diabetes Care.* 1995; 18(9):1260-1265.
4. Aoki TT, Benbarka MM, Okimura MC, et al. Long-term intermittent intravenous insulin therapy and type 1 diabetes mellitus. *Lancet.* 1993; 342(8870):515-518.
5. Hayes Directory. Chronic Intermittent Intravenous Insulin Therapy (CIIT) for Type 1 Diabetes Mellitus. July 14, 2006.

Government Agencies, Professional and Medical Organizations

1. American Association of Clinical Endocrinologists, American College of Endocrinology. Medical guidelines for the management of diabetes mellitus: The AACE system of intensive diabetes self-management--2002 update. *Endocr Pract.* 2002;8(Suppl 1):40-82. Available at: http://www.guideline.gov/summary/summary.aspx?doc_id=3172&nbr=002398
2. American Diabetes Association. Nutrition recommendations and interventions for diabetes: A position statement of the American Diabetes Association. *Diabetes Care.* 2007;30 Suppl 1:S48-S65. Available at: http://www.guidelines.gov/summary/summary.aspx?doc_id=10399&nbr=5445
3. National Collaborating Centre for Chronic Conditions. Type 1 diabetes in adults. National clinical guideline for diagnosis and management in primary and secondary care. London (UK): Royal College of Physicians; 2004. Available at: http://www.guidelines.gov/summary/summary.aspx?doc_id=6249&nbr=004009&string=intravenous+AND+insulin+AND+therapy

HISTORY AND REVISIONS

Date	Action
12/1/2011	<ul style="list-style-type: none">• New template design approved by MPC.
2/26/2011	<ul style="list-style-type: none">• Approved by MPC.