Select Health Medical Policies

Endocrinology Policies

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MEDICAL POLICY

CHRONIC INTERMITTENT IV INSULIN THERAPY (CIIIT), METABOLIC ACTIVATION THERAPY (HEPATIC ACTIVATION THERAPY), OR CELLULAR ACTIVATION THERAPY (CAT)

Policy # 230
Implementation Date: 5/1/04
Review Dates: 4/14/05, 4/20/06, 5/17/07, 4/24/08, 4/23/09, 5/19/11, 6/21/12, 6/20/13, 4/17/14, 5/7/15, 4/14/16, 4/27/17, 9/18/18, 4/19/19, 4/15/20, 4/15/21, 3/17/22, 4/20/23
Revision Dates: 2/8/10

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2. Policies outline coverage determinations for Select Health Commercial, Select Health Advantage (Medicare/CMS), and Select Health Community Care (Medicaid/CHIP) plans. Refer to the "Policy" section for more information.

Description

Hepatic activation, also referred to as chronic intermittent intravenous insulin infusion therapy (CIIIT) or pulsatile IV insulin therapy (PIVIT), is a treatment of diabetes involving the delivery of insulin intravenously over a 6–7-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, one of the principal investigators of CIIIT, 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.

The CIIIT Program consists of a once-a-week treatment session of 6 hours of programmed intermittent intravenous insulin therapy, together with oral glucose. This session uses a complex methodology under the direction of a physician in a healthcare setting. Patients relax in big lounge chairs and read, watch TV, sleep, do crafts, or even work on business projects for the 6 hours. The remainder of the week, the patient follows the American Diabetes Association (ADA) recommended insulin therapy, usually the "4 shot regimen." The patient and physician work in partnership to optimize health with attention to diet, exercise, and treatment of other medical problems such as hypertension.

COMMERCIAL PLAN POLICY/CHIP (CHILDREN'S HEALTH INSURANCE PROGRAM)

Select Health does NOT cover chronic intermittent IV insulin therapy (CIIT), metabolic activation therapy (hepatic activation therapy), or cellular activation therapy (CAT); the long-term health outcomes of our members with regards to these therapies has not been established. This meets the plan's definition of experimental/investigational.

Select Health Advantage (Medicare/CMS)

Coverage is determined by the Centers for Medicare and Medicaid Services (CMS); if a coverage determination has not been adopted by CMS, and InterQual criteria are not available, the

Chronic Intermittent IV Insulin Therapy (CIIIT), Metabolic Activation Therapy (Hepatic Activation Therapy), or Cellular Activation Therapy (CAT), continued

Select Health Commercial policy applies. For the most up-to-date Medicare policies and coverage, please visit their search website http://www.cms.gov/medicare-coverage-database/overview-and-quick-search.aspx?from2=search1.asp& or the manual website

Select Health Community Care (Medicaid)

Coverage is determined by the State of Utah Medicaid program; if Utah State Medicaid has no published coverage position and InterQual criteria are not available, the Select Health Commercial criteria will apply. For the most up-to-date Medicaid policies and coverage, please visit their website http://health.utah.gov/medicaid/manuals/directory.php or the Utah Medicaid code Look-Up tool

Summary of Medical Information

There were no systematic reviews identified for this report and only 3 published clinical trials, 2 of which were controlled, the third a cross-over trial; total sample size for the 3 studies was 149 (including controls) and follow-up ranged from 3–18 months. While these 3 studies demonstrated improvement in the measured outcomes, the total number of patients studied, and short follow-up times prevent making any conclusions about the effectiveness or safety of the therapy.

Aoki and colleagues studied the effect of CIIIT on hypertensive medications in 26 patients with type 1 diabetes and associated hypertension and nephropathy. The 26 patients were randomly assigned to a control group or treatment group for 3 months and then crossed over to the opposite group for an additional 3 months. At baseline, all patients were being treated with 4 daily insulin injections and had achieved acceptable HbA1c levels of 7.4%. The patients also achieved acceptable baseline blood pressure control with a variety of medications. While the study was randomized, it was not blinded in that sham CIIIT procedures were not performed. Therefore, those patients receiving CIIIT received more intense follow-up during this period. During the treatment phase, patients reported a significant decrease in the dosage of antihypertensive medicines. No difference in glycemic control was noted. Since all the patients had adequate blood pressure control at baseline, the clinical significance of the decrease in antihypertensive dosage requirement associated with CIIIT is uncertain.

Dailey and colleagues reported on the effect of CIIIT on the progression of diabetic nephropathy in a prospective, non-randomized trial of 49 patients with Type 1 diabetes. A total of 26 were assigned to the control group, while 23 were assigned to the treatment group who underwent weekly CIIIT. Both groups reported a similar significant decrease in HbA1c levels during the 18-month study period. The creatinine clearance declined in both groups as expected, but the rate of decline in the treatment group was significantly less compared to the control group. Again, the clinical significance of this finding is uncertain, particularly since the decrease in HbA1c was similar in both groups.

All other studies of CIIIT therapy were case series. Additionally, there have been no new studies regarding this therapy since 2001. This suggests that despite the prominence of diabetes and its complications in the US population, academic interest in this therapy is lacking.

Finally, metabolic activation therapy is not discussed as a treatment option in the 2004 clinical practice recommendations of the American Diabetes Association or the American Academy of Clinical Endocrinologists. This suggests that this therapy remains outside the standard of care for the treatment of diabetes or its complications.

A literature review performed in February 2010 identified Medicare's National Coverage Decision for this treatment. They stated the evidence does not support a conclusion that the therapy improved health outcomes.

Billing/Coding Information

Not Covered: Investigational/Experimental/Unproven for this indication

CPT CODES

82947	Glucose; quantitative, blood (except reagent strip)
82948	; quantitative, blood, reagent strip

Select Health

Chronic Intermittent IV Insulin Therapy (CIIIT), Metabolic Activation Therapy (Hepatic Activation Therapy), or Cellular Activation Therapy (CAT), continued

82950	; post glucose dose (includes glucose)
82962	Glucose, blood by glucose monitoring devices(s) cleared by the FDA specifically for home use
84132	Potassium; serum, plasma or whole blood
84133	; urine
84540	Urea nitrogen; urine
96374	Therapeutic, prophylactic, or diagnostic injection (specify substance or drug); intravenous push, single or initial substance/drug
96379	Unlisted therapeutic, prophylactic, or diagnostic intravenous or intra-arterial injection or infusion
94681	Oxygen uptake, expired gas analysis; including CO2 output, percentage oxygen extracted.
94690	Oxygen uptake, expired gas analysis; rest, indirect (separate procedure)

HCPCS CODES

G9147	Outpatient intravenous insulin treatment (OIVIT) either pulsatile or continuous, by any means, guided by the results of measurements for: respiratory quotient; and/or, urine urea nitrogen (UUN); and/or, arterial, venous or capillary glucose; and/or potassium concentration

Key References

1. 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*, 2002; 8(Suppl 1):40-65
2. American Diabetes Association. Clinical Practice Recommendations 2003. *Diabetes Care*, 2003; 26 (Suppl 1).
3. Aoki TT, Benbarka MM, Okimura MC, et al. Long-term intermittent intravenous insulin therapy and type 1 diabetes mellitus. *Lancet*, 1993, Aug 28; 342(8870):515-8.
4. Aoki TT, Grecu EO, Arcangeli MA, Meisenheimer R. Effect of intensive insulin therapy on abnormal circadian blood pressure pattern in patients with type I diabetes mellitus. *Online J Curr Clin Trials*, 1995, Dec 15; Doc No 199.
5. Aoki TT, Grecu EO, Arcangeli MA. Chronic intermittent intravenous insulin therapy corrects orthostatic hypotension of diabetes. *Am J Med*, 1995 Dec;99(6):683-4.
6. Aoki TT, Grecu EO, Prendergast JJ, et al. Effect of chronic ntermittent intravenous insulin therapy on antihypertensive medication requirements in IDDM subjects with hypertension and nephropathy. *Diabetes Care*, 1995 Sep;18(9):1260-5.
7. Dailey GE, Boden GH, Creech RH, Johnson DG, Gleason RE, Kennedy FP, Weinrauch LA, Weir M, D'Elia JA. Effects of pulsatile intravenous insulin therapy on the progression of diabetic nephropathy. *Metabolism*, 2000 Nov; 49(11):1491-5.
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9. Heinemann L. Chronic intermittent intravenous insulin therapy: really a new therapeutic option? *Diabetes Technol Ther*, 2001 SprinQ; 3(1):125-7.
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Chronic Intermittent IV Insulin Therapy (CIIIT), Metabolic Activation Therapy (Hepatic Activation Therapy), or Cellular Activation Therapy (CAT), continued

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MEDICAL POLICY

WHOLE BODY VIBRATION THERAPY (WBVT) FOR THE TREATMENT OF OSTEOPOROSIS

Policy # 516
Implementation Date: 11/4/12
Review Dates: 12/19/13, 12/18/14, 12/10/15, 12/15/16, 12/21/17, 12/19/18, 12/12/19, 12/17/20, 11/18/21, 1/13/23, 12/20/23
Revision Dates:

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Description

The World Health Organization (WHO) defines osteoporosis as a systemic skeletal disease characterized by low bone mass and micro-architectural deterioration of bone tissue with a consequent increase in bone fragility and susceptibility to fracture. Assessment of fracture risk should be part of the clinical evaluation of persons older than 50 years.

Prevention and treatment of osteoporosis consists of lifestyle modification, prescription and non-prescription, hormonal therapy, supplementation, diet, and exercise. There are several pharmaceutical agents commonly used to treat osteoporosis. The most commonly prescribed medications are oral or injectable bisphosphonate medications. These medications have demonstrated an ability to improve bone mineral density and to reduce bone fractures.

As an alternative to pharmaceutical therapies, whole body vibration therapy (WBVT) has been studied. WBVT refers to a procedure in which a patient stands on a platform that produces vibrations. This procedure is purported to increase bone growth, patients with osteopenia (a loss of bone density that is not severe enough to be classified as osteoporosis), and osteoporosis due to its ease of use and increase adherence to treatment. There are 3 main methods in which WBVT stimulation is speculated to increase bone growth: (1) direct stimulation of bone cells; (2) activation of muscles that then contract and stimulate the bone; and (3) strengthening of muscle that then exposes the bone to greater force. WBVT might be considered a special form of muscle training, as it increases neuromuscular activation similar to resistance exercise. However, concern has been raised regarding the safety of WBVT and the potential for adverse side effects (e.g., low back pain), especially in an older adult population.

WBVT may also influence the regulation of bone remodeling indirectly via the endocrine system. WBVT has been shown to acutely alter testosterone and growth hormone levels. Serum testosterone levels have been positively associated with BMD at the ultradistal radius, lumbar spine, and hip regions in healthy men and women. Growth hormone levels decrease with age but increase with exercise. No studies have been published which identify any impact of WBVT on bone fragility fractures.

COMMERCIAL PLAN POLICY/CHIP (CHILDREN'S HEALTH INSURANCE PROGRAM)

Select Health does NOT cover whole body vibration therapy (WBVT) for any indication.
Current evidence does not demonstrate any effect on fracture occurrence and there is no literature comparing WBVT to standard therapies. This meets the plan's definition of experimental/investigational and is considered not medical necessary.

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Whole Body Vibration Therapy (WBVT) for the Treatment of Osteoporosis, continued

Select Health Advantage (Medicare/CMS)

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Select Health Community Care (Medicaid)

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Summary of Medical Information
A Medical Technology Assessment performed in October 2012 identified 6 systematic reviews and 10 peer-reviewed studies related to whole body vibration therapy (WBVT). The oldest article dates to 2004 and the newest was published in 2012. Each of the 6 systematic reviews analyzed, on average, 13 studies, and the average number of participants in each study was 83.6 (range, 28–202). The studies included men, women, postmenopausal women, medicated/unmedicated participants, patients who were taking vitamin D and/or calcium supplements and patients who had and had not already been diagnosed with osteoporosis.

The most recent analysis from Hayes (June 2012), included 9 studies and found that only 1 of the 9 was placebo-controlled and that outcomes from all studies varied greatly irrespective of treatment protocol. In none of the studies was fracture reduction an identified endpoint. This disparity of outcomes is exemplified by the evidence from 1 study suggesting improvement in bone density with just 12 minutes of WBVT weekly, whereas, another study did not show benefit with 140 minutes of WBVT weekly.

The review, by Wysocki et al., published in the *Annals of Medicine* in 2011 probably highlights best the issues related to WBVT and the current evidence. This study's authors made a number of conclusions concerning WBVT for the treatment or prevention of osteoporosis and its comorbidities, as follows:

1. Characteristics of the intervention protocol were not reported consistently across studies.
2. It is unclear whether WBVT should be/could be done reliably at home or in the clinical setting accompanied with adequate patient compliance.
3. It is unclear which populations will be more susceptible to harms.
4. It is unclear which populations will benefit from WBVT.
5. Little scientific evidence evaluates the benefits and harms of WBVT for the prevention and treatment of osteoporosis.
6. The literature lacks clear guidance about the optimal patient population.
7. The scant literature did not establish whether WBVT therapy leads to clinically important increases in bone mineral density or reduces risk for fracture.

Those studies identified in our literature search not included in other systematic reviews did nothing to dissuade Wysocki's conclusions. Lau et al. and Sitja-Rabert et al. showed that in > 896 patients who had WBVT increased muscle strength but did not improve BMD except in the femoral neck. Similarly, Slatkovska et al., Bemben et al., Gusi et al., Humphries et al., and Zha et al. (31% of all the literature contained in this review) did note an increase in bone mineral density of the femoral neck after the treatment period.

Although whole-body vibration platforms have been proposed as a non-pharmacologic therapy for postmenopausal osteoporosis, the available data from randomized trials show minimal to no improvement in bone mineral density with the use of whole-body vibration platforms compared with sham vibration,

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walking, or no treatment. In most trials, data were evaluated per-protocol, rather than intention-to-treat. None of the trials evaluated fracture outcomes. In addition, the safety of vibration therapy in elderly patients has not been carefully examined. Therefore, there are insufficient data to recommend this therapy in postmenopausal women

Billing/Coding Information

CPT CODES

97110	Therapeutic procedure, 1 or more areas, each 15 minutes; therapeutic exercises to develop strength and endurance, range of motion and flexibility
97112	; neuromuscular reeducation of movement, balance, coordination, kinesthetic sense, posture, and/or proprioception for sitting and/or standing activities
97530	Therapeutic activities, direct (one-on-one) patient contact by the provider (use of dynamic activities to improve functional performance), each 15 minutes

HCPCS CODES

No specific codes identified

Key References

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15. Sitja-Rabert, M, Rigau, D, Fort Vanmeerghaeghe, A, et al. (2012). Efficacy of whole body vibration exercise in older people: a systematic review. Disabil Rehabil. 34. 11:883-93.
16. Slatkovska, L, Alibhai, SM, Beyene, J, et al. (2010). Effect of whole-body vibration on BMD: a systematic review and meta-analysis. Osteoporos Int. 21. 12:1969-80.
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Chronic Intermittent IV Insulin Therapy (CIIIT), Metabolic Activation Therapy (Hepatic Activation Therapy), or Cellular Activation Therapy (CAT), continued

82950	; post glucose dose (includes glucose)
82962	Glucose, blood by glucose monitoring devices(s) cleared by the FDA specifically for home use
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94681	Oxygen uptake, expired gas analysis; including CO2 output, percentage oxygen extracted.
94690	Oxygen uptake, expired gas analysis; rest, indirect (separate procedure)

HCPCS CODES

G9147	Outpatient intravenous insulin treatment (OIVIT) either pulsatile or continuous, by any means, guided by the results of measurements for: respiratory quotient; and/or, urine urea nitrogen (UUN); and/or, arterial, venous or capillary glucose; and/or potassium concentration

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1. 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*, 2002; 8(Suppl 1):40-65
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7. Dailey GE, Boden GH, Creech RH, Johnson DG, Gleason RE, Kennedy FP, Weinrauch LA, Weir M, D'Elia JA. Effects of pulsatile intravenous insulin therapy on the progression of diabetic nephropathy. *Metabolism*, 2000 Nov; 49(11):1491-5.
8. Gill G, Williams G. Long-term intermittent intravenous therapy and type 1 diabetes mellitus. Editorial Comment. *Lancet*, 1993 Oct 23;342(8878):1056-7; author reply, 1057-8.
9. Heinemann L. Chronic intermittent intravenous insulin therapy: really a new therapeutic option? *Diabetes Technol Ther*, 2001 SprinQ; 3(1):125-7.
10. Lamb WH. Long-term intermittent intravenous therapy and type 1 diabetes mellitus. *Lancet*, 1993 Oct 23;342(8878):1057; author reply, 1057-8.

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