

## Select Health Medical Policies

## **Endocrinology Policies**

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#### **MEDICAL POLICY**

# CHRONIC INTERMITTENT IV INSULIN THERAPY (CIIIT), METABOLIC 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, 4/11/24

Revision Dates: 2/8/10

#### Disclaimer:

1. Policies are subject to change without notice.

 Policies outline coverage determinations for Select Health Commercial, Select Health Medicare (CMS), and Select Health Community Care (Medicaid) 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 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 AND 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 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 Select Health Commercial policy applies. For the most up-to-date Medicare policies and coverage,

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

please visit their search website <a href="http://www.cms.gov/medicare-coverage-database/overview-and-quick-search.aspx?from2=search1.asp&">http://www.cms.gov/medicare-coverage-database/overview-and-quick-search.aspx?from2=search1.asp&</a> or the manual website

#### **SELECT HEALTH COMMUNITY CARE (MEDICAID)**

Select Health Community Care policies typically align with State of Utah Medicaid policy, including use of InterQual. There may be situations where NCD/LCD criteria or Select Health commercial policies are used. For the most up-to-date Medicaid policies and coverage, please visit their website <a href="http://health.utah.gov/medicaid/manuals/directory.php">http://health.utah.gov/medicaid/manuals/directory.php</a> or the <a href="http://health.utah.gov/medicaid/manuals/directory.php">Utah Medicaid code Look-Up tool</a>

#### **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

**82950** ; post glucose dose (includes glucose)

POLICY # 230 - CHRONIC INTERMITTENT IV INSULIN THERAPY (CIIIT), METABOLIC ACTIVATION THERAPY (HEPATIC ACTIVATION THERAPY), OR CELLULAR ACTIVATION THERAPY (CAT)
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#### Chronic Intermittent IV Insulin Therapy (CIIIT), Metabolic Activation Therapy (Hepatic Activation Therapy), or Cellular Activation Therapy (CAT), continued

82962	Glucose, blood by glucose monitoring devices(s) cleared by the FDA specifically for home use $ \frac{1}{2} \int_{\mathbb{R}^{n}} \frac{1}{2} \int_{\mathbb{R}^{n$
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 guotient; and/or, urine urea nitrogen (UUN); and/or, arterial, venous or capillary glucose; and/or potassium concentration

#### **Key References**

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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**

#### RADIOFREQUENCY ABLATION FOR BENIGN THYROID NODULES

Policy # 646

Implementation Date: 4/17/21

Review Dates: 3/15/22, 4/3/23, 4/17/24

**Revision Dates:** 

#### Disclaimer:

1. Policies are subject to change without notice.

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

Thyroid nodules are common and occur in up to 50% of individuals. Most are benign (non-cancerous) and only require monitoring. However, sometimes even benign nodules become large enough to either cause pressure symptoms in the neck or be otherwise bothersome to the patient. Surgery is then an option, but leaves a scar, and, depending upon the extent of surgery needed, can result in hypothyroidism and rarely problems with the parathyroid glands that control calcium in the blood.

When nodules are cystic, ethanol infusion can be used to decrease the size. However, with solid nodules, other methods, such as radiofrequency ablation (RFA) and laser ablation (LA), have been used.

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

**Select Health covers radiofrequency ablation of thyroid nodules** for symptomatic benign thyroid nodules.

Select Health does not cover radiofrequency ablation of thyroid nodules for cosmetic purposes or as a primary cancer treatment.

#### **SELECT HEALTH MEDICARE**

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

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#### Radiofrequency Ablation for Benign Thyroid Nodules, continued

#### **Summary of Medical Information**

Both RFA and LA have been shown to be effective in many studies including a recent meta-analysis with volume reduction rates at 6 months, 1 year, and 2 years were 68%, 75%, and 87% for RFA and 48%, 52%, and 45% for LA. However, the two techniques have not been compared head-to-head.

This study was done to directly compare RFA and LA in their ability to decrease the size and symptoms of benign, solid thyroid nodules.

#### **Billing/Coding Information**

#### **CPT CODES**

Ablation of 1 or more thyroid nodule(s), one lobe or the isthmus, percutaneous, including

imaging guidance, radiofrequency

Ablation of 1 or more thyroid nodule(s), additional lobe, percutaneous, including imaging

guidance, radiofrequency (List separately in addition to code for primary procedure)

#### **Key References**

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- 10. Orloff, L.A., et al. Radiofrequency ablation and related ultrasound-guided ablation technologies for treatment of benign and malignant thyroid disease: An international multidisciplinary consensus statement of the American Head and Neck Society Endocrine Surgery Section with the Asia Pacific Society of Thyroid Surgery, Associazione Medici Endocrinologi, British Association of Endocrine and Thyroid Surgeons, European Thyroid Association, Italian Society of Endocrine Surgery Units, Korean Society of Thyroid Radiology, Latin American Thyroid Society, and Thyroid Nodules Therapies Association. Head Neck. 2022 Mar;44(3):633-660. doi: 10.1002/hed.26960. Epub 2021 Dec 23. PMID: 34939714.
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#### Radiofrequency Ablation for Benign Thyroid Nodules, continued

treatment. Benefits and eligibility are determined before medical guidelines and payment guidelines are applied. Benefits are determined by the member's individual benefit plan that is in effect at the time services are rendered.

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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, 12/18/24

Revision Dates:

#### Disclaimer:

1. Policies are subject to change without notice.

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

#### 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 people 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 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 AND 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.

POLICY #516 - WHOLE BODY VIBRATION THERAPY (WBVT) FOR THE TREATMENT OF OSTEOPOROSIS



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

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

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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. None of the studies had a fracture reduction at 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 several 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.
- 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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#### Whole Body Vibration Therapy (WBVT) for the Treatment of Osteoporosis, continued

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 ; neuro muscular 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

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Page 3

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

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

82962 Glucose, blood by glucose monitoring devices(s) cleared by the FDA specifically for home

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

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POLICY#230 - CHRONIC INTERMITTENT IV INSULIN THERAPY (CIIIT), METABOLIC ACTIVATION THERAPY (HEPATIC ACTIVATION THERAPY), OR CELLULAR ACTIVATION THERAPY (CAT)
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