



Harmony Behavioral Health, Inc.

Harmony Behavioral Health of Florida, Inc.

Harmony Health Plan of Illinois, Inc.

HealthEase of Florida, Inc.

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WellCare of Texas, Inc.

WellCare Prescription Insurance, Inc.

Insulin Potentiation Therapy

Policy Number: HS-105

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**Revised Date(s): 5/28/2010; 7/18/2011;
5/3/2012**

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

The following text is from the American Cancer Society (2007):

"Insulin potentiation therapy (IPT) refers to the use of insulin along with lower doses of chemotherapy to treat cancer. It is also sometimes used with other treatments for chronic diseases. Despite individual reports, there are no published scientific studies available showing that IPT is safe or effective in treating cancer in humans. IPT may have serious side effects.

Insulin potentiation therapy is promoted as a "kinder, gentler" approach to chemotherapy, with "little to none of the negative side effects of chemotherapy." It purports to use about a tenth of the usual dose of cancer treatment medicine. The effect of the chemotherapy is claimed to be magnified or potentiated by the use of insulin, which lowers the blood sugar. People who offer this treatment claim that insulin "opens up" the receptors on cancer cells so that more chemotherapy can get in. IPT has also reportedly been used to treat fibromyalgia, chronic fatigue syndrome, arthritis, and some infections. Some practitioners use IPT along with other complementary or alternative treatments such as cell therapy.

The patient reports to an IPT clinic after having had nothing to eat or drink other than water for 6 to 8 hours. Intravenous (IV) fluids are started, and the patient is given a dose of insulin based on his or her body weight. For people with cancer, low doses of chemotherapy drugs are given a few minutes later so that they reach the bloodstream after the insulin has started to lower the patient's blood sugar. This is called the "therapeutic moment" by some IPT providers.

At this point, the patient usually has some symptoms of low blood sugar (hypoglycemia). These can be quite severe, especially the first time, because people can respond to a standard dose of insulin quite differently. The IV is switched to a high-sugar solution to raise the blood sugar. After the symptoms of low blood sugar begin to improve, the patient may be given food to raise the blood sugar further. During this process, the blood sugar may be checked by fingerstick.

At the next treatment, the insulin dose may be raised or lowered, depending on the patient's response to the first dose. Between treatments, the patient may be given chemotherapy drugs taken by mouth, and may also get vitamins or other supplements. Treatment is usually given twice a week, generally for 12 to 18 sessions. After the first round of treatment, some people are advised that they need additional "maintenance" sessions.

Some supporters of insulin potentiation therapy recommend using it along with dimethyl sulfoxide (DMSO), a solvent sometimes used to treat a particular bladder problem. Other medicines or supplements may be paired with IPT for patients with illnesses other than cancer. One source was quoted at \$15,500 to \$17,500 for three to four weeks of "intensive IPT."

Insulin was first isolated from pancreatic tissue in the early 1920s and has been used as a conventional treatment for diabetes since that time. In the early 1930s, insulin was used to produce coma for short periods in patients with schizophrenia in an attempt to cure them or reduce symptoms. About 1% of these patients died, however, and survivors often had lifelong complications. This type of treatment for schizophrenia was abandoned in the late 1950s.

IPT was developed in Mexico by Dr. Donato Perez Garcia, Sr., around the same time that insulin had begun to be used in schizophrenics. In fact, some supporters of IPT note that, at this early stage, patients with cancer were also put into insulin comas. Dr. Perez Garcia used this technique to try to treat several types of cancer. His son, Donato Perez Garcia Bellon, and grandson, Donato Perez Garcia, Jr., have followed in his footsteps. A physician from the

United States, Dr. Steven G. Ayre, is a supporter of IPT and has published some descriptions of the theory behind it. More recently, books have been published suggesting that IPT can cure cancer, and some alternative clinics have begun to recommend it.

One very small published study on IPT was done in Uruguay. It included 30 women with breast cancer that was resistant to mainstream therapies. Of these women, 10 received insulin, 10 took the chemotherapy drug methotrexate, and 10 received IPT using both drugs. After 8 weeks, researchers reported that the women in the IPT group had smaller increases in tumor size than either of the other groups. Even though they used lower doses of methotrexate than usual, there were some side effects (mouth sores) noted in the IPT group. This study did not look at survival, quality of life, well-being, or lasting effects. No long-term improvements were shown by this study.

Most of the information about insulin potentiation therapy comes from individual reports. Even among those, however, there is no evidence that the people who reported being helped by IPT were followed for long enough to learn whether the treatment worked.

Despite supporters' claims that insulin potentiation therapy has been well researched, no scientific studies that show safety and effectiveness have been published in available peer-reviewed journals. These claims cannot be verified.

There are also concerns about using lower doses of chemotherapy drugs. When chemotherapy drugs are tested in clinical trials, their effects are carefully monitored to learn which dose will best balance the need to kill cancer cells with the goal of keeping side effects at a tolerable level. There is no evidence that chemotherapy at a fraction of the recommended and tested dose can produce the same effect as the full dose if used with insulin.

Because people respond differently to similar doses of insulin, blood sugar can drop quickly to dangerous levels during IPT. Low blood sugar can cause weakness, shakiness, confusion, rapid heartbeat, sweating, seizures, brain damage, or even death if it is prolonged.

People who are on pills to lower the blood sugar for treatment of diabetes may react more severely to low blood sugar caused by IPT. In addition, several medicines can affect the body's response to blood sugar changes. For example, beta-blocker medicines such as atenolol (Tenormin) and metoprolol (Lopressor) can mask the symptoms of low blood sugar, so the blood sugar may become dangerously low before it is noticed. Sulfa antibiotics (Bactrim and Septra) can make the blood sugar go even lower, as can excessive amounts of alcohol.

The possible effects of insulin potentiation therapy to treat cancer during pregnancy have not been studied. However, chemotherapy drugs are not generally advised during pregnancy. Use of IPT for cancer during pregnancy may harm the fetus.

A few people have severe allergic reactions to certain types of insulin, with reactions including fast heartbeat, low blood pressure, trouble breathing, itching, or rash. Insulin has not been approved by the U.S. Food and Drug Administration (FDA) to lower blood sugar to abnormal levels. Even when used as prescribed, it can be dangerous in some: an estimated 2% to 4% of deaths in people with Type I diabetes are due to low blood sugar.

Relying on this type of treatment alone, and avoiding or delaying standard medical care for cancer, may have serious health consequences.”

POSITION STATEMENT

Insulin Potentiation Therapy **is considered experimental and investigational**. Due to the paucity of evidence this treatment paradigm is not a covered benefit.

CODING

CPT® Codes - No applicable codes

ICD-9-CM Diagnosis Codes - No applicable codes

HCPCS® Codes - No applicable codes

ICD-9-CM Diagnosis Codes - All diagnosis codes are non-covered.

*Current Procedural Terminology (CPT) 2012 American Medical Association: Chicago, IL.®©

REFERENCES

Peer Reviewed - N/A

Government Agencies, Professional and Medical Organizations

1. American Cancer Society. (2009, April 21). Insulin potentiation therapy. Retrieved from www.cancer.com

HISTORY AND REVISIONS

Date	Action
5/3/2012	<ul style="list-style-type: none">• Approved by MPC.
12/1/2011	<ul style="list-style-type: none">• New template design approved by MPC.
7/18/2011	<ul style="list-style-type: none">• Approved by MPC.