INSTRUCTIONS FOR USE

The following Coverage Policy applies to health benefit plans administered by Cigna companies. Coverage Policies are intended to provide guidance in interpreting certain standard Cigna benefit plans. Please note, the terms of a customer’s particular benefit plan document [Group Service Agreement, Evidence of Coverage, Certificate of Coverage, Summary Plan Description (SPD) or similar plan document] may differ significantly from the standard benefit plans upon which these Coverage Policies are based. For example, a customer’s benefit plan document may contain a specific exclusion related to a topic addressed in a Coverage Policy. In the event of a conflict, a customer’s benefit plan document always supersedes the information in the Coverage Policies. In the absence of a controlling federal or state coverage mandate, benefits are ultimately determined by the terms of the applicable benefit plan document. Coverage determinations in each specific instance require consideration of 1) the terms of the applicable benefit plan document in effect on the date of service; 2) any applicable laws/regulations; 3) any relevant collateral source materials including Coverage Policies and; 4) the specific facts of the particular situation. Coverage Policies relate exclusively to the administration of health benefit plans. Coverage Policies are not recommendations for treatment and should never be used as treatment guidelines. In certain markets, delegated vendor guidelines may be used to support medical necessity and other coverage determinations. Proprietary information of Cigna. Copyright ©2014 Cigna

Coverage Policy

Many benefit plans specifically exclude dietary/nutritional supplements, vitamins, over-the-counter products, massage therapy, craniosacral therapy, dance/movement therapy, acupressure, rolfing, applied kinesiology, hypnosis and services that are educational, training, and behavioral training in nature. Please refer to the applicable benefit plan document to determine benefit availability and the terms, conditions and limitations of coverage.

For information on Acupuncture and Biofeedback, refer to the applicable Cigna Coverage Policies.

Cigna does not cover the following complementary or alternative medicine diagnostic testing methods, systems, therapies or treatments because each is considered experimental, investigational or unproven (these lists may not be all-inclusive):

- Diagnostic testing methods
  - applied kinesiology (AK)
- chemical hair analysis
- Greek cancer cure test
- iridology
- live blood cell analysis
- nutrient panel testing, including micronutrient panel testing
- antioxidant function testing (e.g., Spectrox™)
- Ream's Testing
- salivary hormone panels

- **Whole medical systems**
  - Ayurveda
  - homeopathy
  - macrobiotics
  - naprapathy
  - naturopathy
  - polarity therapy

- **Biologically-based practices**
  - antineoplastons
  - auto urine therapy
  - cellular therapy
  - Coley's Toxin
  - fecal bacteriotherapy
  - hydrogen peroxide, intravenous
  - immunoaugmentive therapy
  - Kelley-Gonzales therapy
  - Laetrile
  - megavitamin therapy
  - MTH-68
  - ozone therapy
  - Revici’s Guided Chemotherapy
  - Trichuris suis ova therapy
  - over-the-counter biologics (e.g., glucosamide, coenzyme Q10, fish oil [omega-3 fatty acids])

- **Energy medicine**
  - acupressure
  - biofield therapeutics
  - crystal healing
  - cupping
  - gemstone therapy
  - magnet therapy
  - meridian therapy
  - millimeter wave therapy
  - moxibustion therapy
  - Qigong Longevity
  - Reiki
  - therapeutic touch

- **Manipulative and body-based methods**
  - Alexander’s technique
  - AMMA Therapy®
  - colonic irrigation, colonic lavage, colonic cleansing
  - craniosacral therapy
ear candling
Feldenkrais therapy
inversion therapy
myotherapy
neural therapy
Pfrimmer Deep Muscle Therapy®
Pilates
reflexology (zone therapy)
remedial massage
Rolfing
Trager®
Tui Na
visceral massage

• Mind-body medicine
  art therapy
  bioenergetics’ analysis
  Chung Moo Doe therapy martial art
color therapy
dance movement therapy
equestrian therapy (hippotherapy)
faith healing
guided imagery interactive
Hellerwork
humor therapy
hypnosis
meditation/Transcendental Meditation (TM®)
mirror box therapy
music therapy
primal therapy
psychodrama
yoga

Coverage of prescription medications is generally subject to a separate pharmacy benefit. Many pharmacy and medical benefit plans specifically exclude coverage of over-the-counter (OTC) medications, including OTC vitamins and nutritional and dietary supplements.

General Background

Complementary and alternative medicine (CAM), also called unconventional, nonconventional, or nontraditional healthcare, is a group of diverse medical and healthcare systems, practices and products that are not typically considered to be part of traditional Western medicine (i.e., conventional medicine). CAM assessments and therapies are proposed to reduce disease-based clinical symptoms and improve health and wellness. Complementary medicine may be used in conjunction with Western medicine, as opposed to alternative medicine which may be used in place of Western medicine. Integrative medicine, as defined by the National Center for Complementary and Alternative Medicine (NCCAM), combines conventional medical therapies and CAM therapies for which there is scientific evidence of safety and effectiveness. Various CAM therapies are supported by some degree of scientific evidence, but for most CAM therapies key questions regarding the safety and efficacy of these therapies for specific conditions are yet to be answered through well-designed scientific studies (NCCAM, 2012).

Classifications of CAM practices include the following:
• **Whole Medical Systems:** Whole medical systems are built upon complete systems of theory and practice. Often, these systems have evolved apart from, and earlier than, the conventional medical approach used in the United States.

• **Biologically-Based Practices:** Biologically based practices in CAM use substances found in nature including herbs, foods, and vitamins. Examples of these substances include dietary supplements, herbal products, and other natural products that have not been scientifically proven (e.g., using shark cartilage to treat cancer).

• **Energy Medicine:** Energy medicine involves the use of energy fields and consist of two types of therapies:
  - Biofield therapies are intended to affect energy fields that purportedly surround and penetrate the human body. The existence of such fields has not yet been scientifically proven. Some forms of energy therapy are proposed to manipulate biofields by applying pressure, heat or body manipulation.
  - Bioelectromagnetic-based therapies involve the unconventional use of electromagnetic fields, such as pulsed fields, magnetic fields, or alternating current or direct current fields.

• **Manipulative and Body-Based Methods:** Manipulative and body-based methods are based on manipulation and/or movement of one or more parts of the body.

• **Mind-Body Medicine:** Mind-body medicine uses a variety of techniques designed to enhance the mind's capacity to affect bodily function and symptoms.

**U.S. Food and Drug Administration (FDA)**
The Federal Food and Drug Act of 1906, The Wiley Act, empowers the FDA Center for Food Safety and Nutrition to remove unsafe food substances and botanicals from the market, and gives the FDA regulatory oversight for substances added to food, including monitoring safe use. The FDA maintains that a drug is any substance or mixture of substances intended for the cure, mitigation, diagnosis or prevention of disease (FDA, 2009).

Dietary supplements are regulated differently than prescription and over-the-counter drug products. Manufacturers of dietary supplements are responsible for ensuring that their products are safe. While the FDA monitors adverse effects after dietary supplement products are on the market, newly marketed dietary supplements are not subject to premarket approval or a specific post-market surveillance period. Per the Dietary Supplement Health and Education Act of 1994 (DSHEA), the burden of proof rests on the FDA to show that a product is unsafe. Manufacturers are not required to submit substantiation of benefit data to the FDA. The Federal Trade Commission (FTC) is charged with accurate marketing and advertising claims.

According to the FDA, dietary supplements in today’s market include one or a combination of: vitamins, minerals, herbs, botanicals, amino acids, any dietary substance used to supplement the diet by increasing total dietary intake, and a concentrate, metabolite, constituent or extract. The FDA states that, while some supplements may help ensure that the individual consumes adequate amounts of essential nutrients needed for optimal health and performance, dietary supplements cannot be promoted as a treatment or a cure.

In December 2006, the FDA issued a draft guidance document for the regulation of CAM products. The draft was issued because increased use of CAM in the United States has caused confusion regarding which products are subject to regulation under the Federal Food, Drug, and Cosmetic Act (Act) or the Public Health Service Act (PHS Act) and because the number of CAM products being imported into the United States has increased. The document provides guidance as to when a CAM product is subject to the Act or the PHS Act. The FDA cites the NCCAM’s definition and categories of CAM in the draft. According to the new guidance, if the labeling of a dietary supplement includes the term “to treat,” that supplement will be regulated as a drug under the Act. Biological products (e.g., virus, therapeutic serum, toxin, antitoxin, vaccine) will be regulated under the PHS Act (FDA, 2010; FDA, 2007).
Diagnostic Testing Methods

Applied Kinesiology (AK): AK is a form of diagnostic testing that uses muscle testing as a functional neurological evaluation. According to their guidelines on allergy diagnostic testing, the American Academy of Allergy, Asthma and Immunology and the American College of Allergy, Asthma and Immunology stated there is “no evidence of diagnostic validity” of AK (Bernstein, et al., 2008).

Chemical Hair Analysis: Chemical hair analysis is a test in which a person’s hair is analyzed for mineral content. Hair analysis has been proposed to aid in the evaluation of a person’s general state of health, mental and physical conditions (e.g. autism, cancer, hypertension, myocardial infarction, kidney disease, osteoarthritis and diabetes mellitus), skin diseases (e.g., alopecia), detect heavy metals (e.g., lead, mercury, arsenic) and pesticides, identify nutritional/mineral deficiencies, analyze deoxyribonucleic acid (DNA), identify the presence of illegal drugs (e.g., cocaine, marijuana) (Wolowiec, et al., 2013; Caprara, et al., 2006; Balikova, 2005). However, evidence to support the accuracy and clinical utility of hair analysis is lacking.

Greek Cancer Cure: Greek cancer cure also known as METBAL®, Cellbal®, and Alivizatos, consists of a blood test that allegedly diagnoses the location and extent of cancer in a person's body. Following diagnosis, treatment consists of intravenous injections of a serum containing sugars, vitamins, amino acids, and other factors. The American Cancer Society (ACS) stated “available scientific evidence does not support claims that the Greek Cancer Cure is effective in preventing, detecting, or treating cancer (ACS, 2008).

Iridology: Iridology sometimes referred to as iris diagnosis, is based on the belief that each area of the body is represented by a corresponding area in the iris of the eye. According to their guidelines on allergy diagnostic testing, the American Academy of Allergy, Asthma and Immunology and the American College of Allergy, Asthma and Immunology stated there is “no evidence of diagnostic validity” of iridology (Bernstein, et al., 2008).

Live Blood Cell Analysis: Live blood cell analysis by dark field microscopy is an unproven means to study the "biologic terrain" and offer practical, nutritional, herbal, lifestyle solutions for various medical conditions. It involves taking a drop of blood and viewing it under a microscope using a dark field condenser, allowing the viewer to see all components of the blood and tiny particles to enable early detection of disease. There is insufficient evidence to support the accuracy and clinical utility of live blood cell analysis.

Nutrient Panel Testing: Nutrient panel testing assesses the level of multiple nutrients in the body. These panels may include measurement of numerous vitamins, minerals, amino acids, fatty acids, oxidation products, organic acids, toxins and antioxidants. The test results are proposed to help determine the cause of various symptoms, such as hair loss and fatigue, and various disease processes. Antioxidant function testing (e.g., Spectrox™) has been proposed as a method to evaluate the ability of cells to resist damage caused by free radicals and other forms of oxidative stress. SpectraCell Laboratories, Inc., (Houston, TX) offers a micronutrient testing panel proposed to measure how micronutrients function with the white blood cell. The Individual Optimal Nutrition (ION) (Genova Diagnostics, Asheville, NC) is a blood test that measures levels of vitamins, minerals, antioxidants, and organic, fatty and amino acids. ExaTest®, offered by IntraCellular Diagnostics, Inc® (Bedford, OR) is an intracellular tissue analysis of mineral electrolytes. The test is proposed to provide information on mineral electrolyte deficiencies or imbalances not available by blood testing. The analysis is made from an epithelial cell scraping from the sublingual area. The sample is analyzed using high energy photos (x-rays).

At this time, there is insufficient evidence in the published, peer-reviewed, scientific literature to establish the clinical utility of nutrient panel testing or antioxidant function testing or to demonstrate that the use of such testing results in improved health outcomes.

In their practice parameter for the screening and diagnosing of autism, the American Academy of Neurology and the Child Neurology Society stated that there is insufficient evidence to support testing for micronutrients such as vitamin levels (Filipek, et al., 2000; posted 2013).

Ream’s Testing: Ream's Testing is promoted as a noninvasive investigation of the body's overall metabolic function, utilizing urine and saliva samples. An individual's pancreatic function, blood sugar control, pH levels, digestive function, liver function, hydration status, mineral status, kidney and adrenal function, and systemic inflammation are reviewed with recommendations made for diet, specific pH and supplementation of other nutrients. It is used by proponents to monitor progress with various treatment regimes. There is insufficient evidence to support the accuracy and clinical utility of Ream’s testing.
Salivary Hormone Panels
Salivary testing for various hormones in the form of hormone panels (i.e., testing several different hormone levels in one test at the same time) has been proposed for numerous indications including screening and monitoring of menopause, aging and various other conditions. Diagnos-Techs™, Inc. (Kent, WA) offers several different types of these hormone panels including four Menopausal Hormone Panels™. The Postmenopause Panel™ (PostM™) is a diagnostic study that measures estrone (E1), estradiol (E2), estriol (E3), progesterone (P), testosterone (T), dehydroepiandrosterone (DHEA), and dehydroepiandrosterone–sulfate (DHEA-S) (pooled). The Perimenopause Panel™ (PeriM™) measures the same six hormones as the PostM Panel but two samples are analyzed 13-15 days apart. The initial sample is obtained, frozen and sent for analysis with the second sample. The expanded Postmenopause Panel (ePostM™) and the expanded Perimenopause Panel (ePeriM™) include analyses of follicle-stimulating hormone (FSH) and luteinizing hormone (LH) in addition to the six hormones offered in the nonextended panels. Proposed clinical applications of these tests include: to monitor women who are perimenopausal, postmenopausal or have had a total hysterectomy; to aid in risk assessment of breast/uterine proliferative diseases; to detect early disruption in the hypothalamic pituitary ovarian axis in women approaching menopause; to monitor FSH and LH and/or investigate libido changes and emotional vulnerability problems (Diagnos-Tech, 2012).

Diagnos-Techs also offers Male Hormone Panels™ performed on saliva samples. The regular Male Hormone Panel™ (MHP™) is proposed to evaluate the androgen pathway by measuring progesterone, DHEA, DHEA-S, androstenedione, estrone and testosterone. The Expanded Male Hormone Panel™ (eMHP™) includes the six hormones plus FSH and LH. The proposed clinical utility of the test is to diagnose andropause and hypogonadism; monitor hormone replacement therapy and balancing of hormones; investigate prostate hypertrophy, thinning of hair and hirsutism; and evaluate low-libido.

The Adrenal Stress Index™ (ASI), which analyzes four saliva samples, is proposed for evaluation of chronic stress and fatigue, glycemic dysregulation, and chronic pain and inflammation. The ASI test includes cortisol; DHEA-S, 17-Hydroxyprogesterone, two insulin tests (fasting and after meals), secretory IgA (SigA), and gliadin antibodies for grain intolerance. The proposed indications for ASI are to evaluate stress and conditions associated with adrenal disturbances such as chronic pain/fibromyalgia, chronic fatigue syndrome, glycemic dysregulation, allergies, autoimmune disorders, depression and attention deficit disorders.

The Bone Health Panel™ (BHP™) saliva test includes: progesterone, estradiol, testosterone, cortisol, FSH and DHEA/DHEA-S and as a bone marker, deoxypyridinoline (DPD) in urine. The panel is proposed for screening and monitoring for osteoporosis, identifying high risk hip fracture patients and screening for metabolic bone diseases, rheumatoid arthritis and other connective tissue disease, Paget’s disease and bone malignancies.

In guidance, compliance and regulatory information regarding menopausal hormone therapy and “bio-identical” hormones, the U.S. Food and Drug Administration (FDA) (2010), stated that although saliva testing is proposed to help practitioners estimate and “customize” the amount of hormone (i.e., estrogen) a person needs, there is “no scientific basis for using saliva testing to adjust hormone levels”. Adjustment in hormone therapy should be based on the patient’s symptoms.

There is insufficient evidence in the published peer-reviewed literature to support the clinical utility (e.g., appropriate medication dosage, diagnosis and monitoring menopause, risk assessment) of salivary hormone panels. Studies comparing salivary hormone panels to established individual hormone serum testing and impact on health outcomes are lacking.

In 2011 guidelines on the diagnosis and treatment of menopause, The American Association of Clinical Endocrinologists (AACE) stated that salivary hormone level testing is recommended by many bioidentical hormone proponents as a means of providing patients with “individualized” therapy, but the methods are not approved by either the FDA or the Clinical Laboratory Improvement Amendments (CLIA). AACE noted that “accurate studies have revealed large intrasubject variability in salivary sex hormone concentrations which fluctuate depending on numerous variables (e.g., diet, hydration, circadian rhythm).

In a 2012 Committee Opinion on compounded bioidentical hormones (e.g., dehydroepiandrosterone, pregnenolone, testosterone, progesterone, estrone, estradiol, and estriol), the American College of Obstetricians and Gynecologists (ACOG) stated that “there is no evidence that hormonal levels in saliva are
biologically meaningful" and currently, the testing does not offer an "accurate or precise method of hormone testing". ACOG goes on to explain that salivary levels do not consistently provide a reasonable representation of endogenous, circulation serum hormones because of the large variability in salivary hormones depending on diet, time of testing and the hormone being tested. Because the pharmacokinetics of exogenously administered compounded hormones cannot be known, it is not possible to estimate with reliability how and when to test saliva to obtain a representative result. Lastly, saliva contains far lower concentrations of hormone than serum and is prone to contamination with blood, infections agents, and epithelia cells which may affect the level of hormone to be measured. "Hormone levels should not be titrated to hormone levels (serum, urinary, or salivary)."

**Whole Medical Systems**

**Ayurveda:** Ayurveda provides an integrated approach to preventing and treating illness through lifestyle, based upon the premise that all disease begins with an imbalance or stress in the individual's consciousness. Lifestyle interventions are a major Ayurvedic preventive and therapeutic approach and include diet and herbal remedies. This approach emphasizes the use of body, mind and spirit in disease prevention and treatment.

**Homeopathy:** Homeopathy is complementary and alternative medicine system that has been proposed to assist the body's efforts to heal physically, mentally and emotionally. This system encompasses the belief that "like cures like", meaning that small, highly diluted quantities of medicinal substances are given to cure symptoms, when the same substances given at higher or more concentrated doses would actually cause those symptoms. There are over 3000 homeopathic remedies. Homeopathic intravenous (IV) therapy or IV nutrient therapy is the intravenous administration of multiple minerals, vitamins, amino acids, chelating agents, botanical and/or herbal supplements to allow maximum concentrations of these substances in the body. IV therapy has been proposed for the treatment of cancer, malabsorption syndromes (e.g., Crohn's, colitis), metal toxicities, infectious diseases (e.g., Epstein Barr, Lyme disease), and neurological disorders.

Posadzki et al. (2012) conducted a systematic review of case series and case reports to evaluate adverse effects (AEs) of homeopathy. Thirty-five case studies (n=1159) met inclusion criteria. Direct AEs included abdominal pain, acute pancreatitis, severe allergic, and nausea and vomiting. Occasionally homeopathy was reported to result in serious outcomes (e.g., cancer, cardiac arrest, coma, death). Multiple indirect AEs (e.g., hypertension, seizures, organ failure) were also reported. The duration of AEs ranged from 22 hours to seven months with four reported deaths.

Davidson et al. (2011) conducted a systematic review of randomized placebo-controlled trials (n=25) of homeopathy for psychiatric conditions (i.e., anxiety, depression, sleep problems, attention-deficit/hyperactivity disorder (ADHD), premenstrual syndrome (PMS), mild traumatic brain injury (TBI) and somatic spectrum disorders. Efficacy was reported for fibromyalgia and chronic fatigue syndrome but not for anxiety or stress. Mixed effects were reported for the other disorders. No studies were found for depression. Meta-analysis could not be performed due to the limited number of studies and heterogeneity of the data sets. The authors concluded that firm conclusions about the safety and efficacy of homeopathy for any of these conditions could not be made.

**Macrobiotics:** Macrobiotics is the art and science of health and longevity through the study and understanding of the relation and interactions between oneself, foods, lifestyles and the environment.

**Naprapathy:** Naprapathy or naprapathic medicine is a system that employees manual medicine (e.g., spinal manipulation), nutritional counseling and therapeutic modalities (e.g., heat, cold, ultrasound, electrical stimulation) for the treatment of pain caused by connective tissue disorders (American Naprapathic Association, 2014).

**Naturopathy:** Naturopathy is a system of healing that views disease as a manifestation of alterations in the processes by which the body naturally heals itself. It emphasizes health restoration as well as, disease treatment. The core modalities utilized include diet modification, nutritional supplements, herbal medicine, acupuncture, Chinese medicine, hydrotherapy, massage, joint manipulation, and lifestyle counseling.

Two Cochrane systematic reviews of randomized or quasi-randomized controlled trials reported on the effects of Chinese herbal medicine (CHM) for endometriosis and threatened abortion. Although two studies (n=158) suggested that CHM might be useful in relieving endometriosis pain, the trials were of poor methodological
quality and the authors noted that the outcomes “must be interpreted cautiously” (Flower, et al., 2012). Li et al. (2012) investigated the effects of CHM for the treatment of threatened abortion. A total of 44 trials (n=5100) met inclusion criteria. There was insufficient evidence to assess the effectiveness of CHM alone for this indication.

**Polarity Therapy:** Polarity therapy is a comprehensive health system involving energy-based bodywork, diet, exercise and self-awareness. It works with the human energy field and the electro-magnetic patterns expressed in mental, emotional and physical experience. According to ACS (2008), “claims that polarity therapy is an effective treatment for cancer and other serious diseases have not been proven.”

**Biologically-Based Practices**

**Antineoplastons:** Antineoplastons are a group of synthetic compounds originally isolated from human blood and urine. They include five urinary antineoplastons (i.e., A–1 to A–5) that have been theorized as having antineoplastic activity against cancer. Antineoplastons are not approved for use by the FDA.

**Auto Urine Therapy:** Auto urine therapy purports to purge embedded toxins and parasites from the colon, bloodstream, arteries and internal organs, simply by drinking one’s own urine. There is insufficient evidence to support the effectiveness of this therapy.

**Cellular Therapy:** Cellular therapy, also called live cell therapy, cellular suspensions, glandular therapy, fresh cell therapy, siccacell therapy, embryonic cell therapy and organotherapy, refers to various procedures in which processed tissue from animal embryos, fetuses or organs is injected or taken orally. Those who practice cell therapy believe that cell therapy acts like an organ transplant, having a rejuvenation effect.

Although proposed for the treatment of cancer, the American Cancer Society (ACS) stated no evidence has been found to support the effectiveness of cellular therapy. The Cancer Society stated that “cell therapy may be dangerous, and several cases have been reported in the medical literature of patient deaths directly linked to the therapy. Patients may contract bacterial and viral infections carried by the animal cells, and some have experienced life-threatening and even fatal allergic reactions” (ACS, 2008).

**Coley's Toxin:** Coley's Toxin, also known as mixed bacterial vaccine (MBV) and Issel's fever therapy, is a treatment for cancer devised by Dr. William Coley. The toxins are the fluids derived from a bacterial culture of two microorganisms, streptococcus pyogenes and serrata marcescens and are injected into affected tissue to initiate a high fever, causing necrosis of cancer tissue. A major problem reported with bacterial therapy is their toxicity when used at the dose required for therapeutic efficacy, including the risk of systemic toxicities (Patyar, et al., 2010).

**Fecal Bacteriotherapy:** Fecal bacteriotherapy, fecal microbiota, fecal microbiota transplantation (FMT), fecal transfusion, or probiotic infusion is the transfer of a liquid suspension of stool from a healthy donor to the patient and is proposed for the treatment of Clostridium difficile infection (CDI). CDI can result in mild diarrhea to life-threatening fulminant pseudomembranous colitis. Treatment involves discontinuation of the offending antibody and oral administration of metronidazole or vancomycin. In some cases, patients nonresponsive to medical management are treated by surgical colectomy which has a morality rate of 35%-57%. The stool can be delivered by various methods including capsules, colonoscopy, nasogastric tube and enema. One of the risks with fecal bacteriotherapy is the transfer of infectious agents (e.g., viruses, fungi, parasites) from the donor. Other concerns about FMT are that the optimal donor-feces infusion protocol has not been defined, and the amount of feces required and the effects of varying potential routes of infusion are unknown (Van Nood, et al., 2013; Bakken, et al., 2009; You, et al., 2008).

In 2013, the U.S. Food and Drug Administration issued a guidance document for immediate implementation for fecal microbiota transplantation (FMT) for the treatment of C. difficile infection not responsive to standard therapies. Because FMT is being used to treat/cure a condition and is considered an unapproved new drug for which an Investigational New Drug (IND) application is required, the FDA is exercising enforcement discretion regarding the IND requirements for this therapy. This is an interim measure until such time that the FDA develops appropriate policies for clinical trials and use of FMT products under the IND. This type of guidance describes the FDA’s current thinking on a topic and is only a recommendation, unless specific regulatory or statutory requirements are cited. FDA noted that the safety and efficacy of FMT has not been fully evaluated in controlled clinical trials. The use of FMT and clinical studies to evaluate its safety and effectiveness are subject
to regulation by FDA. The FDA pointed out that the complex nature of FMT products presents specific scientific and regulatory challenges (FDA, 2013).

Van Nood et al. (2013) conducted a randomized controlled trial including 43 volunteer subjects to determine the effect of duodenal infusion of donor feces in patients with recurrent C. difficile. Patients, age 18 years or older, had a life expectancy of three months or longer and had experienced a relapse of C. difficile infection following at least one course of vancomycin or metronidazole. C. difficile infection was defined as ≥ 3 loose or watery stools per day for at least two consecutive days or ≥ 8 loose stools in 48 hours and a positive stool test for C. difficile. The three study groups were treated with the infusion of donor feces preceded by an abbreviated regimen of vancomycin (4–5 days) and bowel lavage (n=17), vancomycin only (n=13) or vancomycin and bowel lavage (n=13). One dose of a suspension of donor feces through a nasoduodenal tube was administered to the study group. If C. difficile returned after the first donor-feces infusion, a second infusion was given. The study was stopped after an interim analysis. Sixteen infusion patients were cured after the first infusion with two additional patients cured after a second infusion. Four patients in the vancomycin only group and three in the vancomycin/lavage group were cured. Significantly more patients were cured with fecal infusion compared to the control groups (p<0.001, each). Five weeks following the initiation of therapy one patient in the infusion group, eight in the vancomycin group and seven in the vancomycin/lavage group experienced recurrence of C. difficile. Eighteen patients in the antibiotic groups where treated with off-protocol infusions and 15 were cured, four after two infusions. Adverse events in the infusion group included diarrhea, cramping and belching within the first three hours following infusion. Limitations of the study include the small patient population, infusion group also received vancomycin and lavage, and early cessation of the study. The authors noted that because most patients had several relapses before study inclusion, typically following vancomycin therapy, the efficacy of vancomycin was “considerably lower than expected”.

ECRI (2013) conducted a systematic review to evaluate the evidence for fecal microbiota transplantation (FMT) for treating recurrent or relapsing Clostridium difficile infection (CDI). Ten retrospective reviews, one case series (n=256) and one randomized controlled trial met inclusion criteria. The studies reported on patients with recurrent or relapsing Clostridium difficile infection (CDI). The studies reported that fecal transplant was an effective treatment in 72%-100% of the patients. However, given the prevalence of CDI, more randomized controlled trials are indicated to compare FMT to established treatment options (e.g., antibiotics). In addition to the retrospective study design, limitations of the studies included the lack of comparison to standard therapies, short-term follow-ups and variations in protocols for stool donors, stool preparation, route of administration, and definition of response.

Guo et al. (2012) also conducted a systematic review to evaluate the safety and effectiveness of fecal transplant (FT) compared to standard treatment for Clostridium difficile-associated disease (CDAD). No controlled studies were found. Seven case series (n=124) met inclusion criteria. The authors stated that treatment effects of FT for this condition could not be determined in the absence of controlled studies comparing FT to standard therapy (e.g., vancomycin).

Guidelines for the management of C. difficile by the American College for Gastroenterology (ACG) (2013) stated that FMT should be considered if there is a third recurrence following a pulsed vancomycin regimen. ACG notes that long-term follow-up is limited and the potential for transmission of infectious agents is a concern. This is a conditional recommendation (uncertainty exists about the risk-benefit ratio) based on moderate-quality evidence.

**Hydrogen Peroxide:** Hydrogen peroxide given intravenously is proposed to kill or inhibit bacteria and viruses, precluding the need for antibiotic therapy. It may be given as a treatment for the common cold, influenza and sinus infections. It is also proposed by some as a treatment modality for acquired immune deficiency syndrome (AIDS) and cancer.

**Immunoaugmentive Therapy (IAT):** IAT is an experimental form of cancer immunotherapy consisting of daily injections of processed blood products. It is a developing treatment for mesothelioma that seeks to strengthen the body’s natural immune system by balancing four blood proteins.

**Kelley-Gonzales Therapy:** Kelley-Gonzales Therapy is based on belief in a relationship between diet and detoxification with coffee enemas. According to Kelley, all cancers are one disease caused by a deficiency of protein digestive enzymes which allows cancer cells to grow.
Laetrile: Laetrile is the trade name for laevo-mandelonitrile-beta-glucuronoside. The compound is chemically related to amygdalin, a substance found naturally in the pits of apricots and various other fruits. Laetrile is proposed for the treatment of cancer due to its ability to selectively kill cancer cells without being toxic to normal cells. The ACS stated that “the consensus of available scientific evidence does not support claims that laetrile is an effective anti-cancer treatment, either in animal studies or in human clinical trials” (ACS, 2012).

Megavitamin Therapy: Megavitamin therapy, orthomolecular medicine, megamineral therapy, intravenously or orally, is the use of vitamins, minerals or hormones in amounts considerably greater than the recommended daily allowance in the belief that abundant use of vitamins can prevent or cure various ailments. The ACS discourages the use of vitamins or supplements beyond the recommended levels. There is no evidence that supplements lower the chance of cancer coming back or improved survival (ACS, 2008).

MTH-68: MTH-68 (i.e., more than hope-68) vaccine is a nonpathogenic virus (i.e., Newcastle disease virus [NDV]) that is believed to interfere with cancer growth in humans. The virus is reported to enhance the immune system and selectively kill cancer cells. According to the NCI, “NDV-based anticancer therapy has been reported to be of benefit in more than a dozen clinical studies, but the results of these studies must be considered inconclusive because the study designs were weak and the study reports were generally incomplete” (NCI, 2014).

Ozone Therapy: Ozone therapy also known as oxygen therapies or oxidative therapies include the following speculative restorative uses: autohemotherapy, auricular insufflation, colonics, intramuscular, intra-arterial, ozonated olive oil, ozonated steam, ozonated water, rectal insufflation and hydrogen peroxide. It is proposed that the extra oxygen increases the body's ability to destroy disease-causing cells.

Magalhaes et al. (2012) conducted a systematic review and meta-analysis to evaluate the effectiveness of percutaneous injections of ozone for the treatment of low back pain secondary to disc herniation. Four randomized controlled trials (n=306) and eight observations studies (n=6699) met inclusion criteria. From the randomized studies, intervention was found to be superior to the control (e.g., sham, steroid or steroid with local anesthetic) (p<0.00001). Overall, the observational studies revealed positive results for short- and long-term relief of pain. Complications were rarely documented. The indicated level of evidence for long-term pain relief (≥ 6 months) was II-3 (evidence from diagnostic studies of uncertainty) for ozone therapy applied intradiscally, II-1 (evidence from at least one properly conducted diagnostic accuracy study of adequate size) for ozone therapy applied paravertebrally, 1C (strong recommendation, low-quality or very low quality evidence) for intradiscal ozone therapy and 1B (strong recommendation, moderate quality evidence) for paravertebral ozone therapy. Limitations of the studies included a lack of precise diagnosis, use of mixed therapeutic agents, and short-term follow-up.

Revici’s Guided Chemotherapy: Revici’s guided chemotherapy, also known as biologically guided chemotherapy, Revici’s cancer control, lipid therapy, or Revici’s method, is a chemical therapy given by mouth or injection. It is promoted as an alternative cancer treatment, as well as treatment for heart disease, arthritis, AIDS, chronic pain, drug addiction, injury from radiation, and schizophrenia. The therapy varies for every patient, but can include a chemical formulation consisting of lipid alcohols, caffeine, zinc and iron, or a formulation consisting of fatty acids, selenium, magnesium and sulfur. The ACS states that “Revici’s guided chemotherapy for cancer has never been proven to be safe or effective” (ACS, 2008).

Trichuris Suis Ova Therapy: Trichuris suis ova, T suis ova, ova worm, or porcine whipworm, therapy is a form of helminth immunomodulation or ova therapy. Helminths (i.e., worms) have the capacity to prevent excessive inflammatory responses and inhibit immune responsiveness, including gastrointestinal inflammation as seen in ulcerative colitis and Crohn’s disease (Summers, 2007). Ova therapy is also being evaluated for the treatment of multiple sclerosis, allergic rhinitis and autism spectrum disorders (Rosche, et al, 2013; Siniscalco and Antonucci, 2013).

Bager et al. (2010) conducted a randomized controlled trial to determine the efficacy of T suis ova for the treatment of allergic rhinitis (n=100). No therapeutic effect was reported and significant gastrointestinal adverse events (p=0.007) (e.g., diarrhea and abdominal pain) occurred in 76% of the T suis group compared to 49% in the placebo group. Summers et al. (2005) (n=54) reported at 12-weeks follow-up that a significant improvement (p=0.4) was seen with ova therapy compared to placebo in patients with active ulcerative colitis. The placebo
group showed significant improvement in stool frequency (p=0.0488) compared to baseline. Limitations of the study include the small patient population and the short-term follow-up.

**Over-the-Counter Biologics:** Over-the-counter biological products include the following (this list may not be all inclusive):

- Actra-Rx (Yillshen)
- Apitherapy
- Aromatherapy
- Bilberry
- Black Cohosh (cimicifuga racemosa, rattle root, snake root)
- Bovine Cartilage Products
- Cancell/Entelev (Sheridan’s Formula, Jim’s Juice, Crocinic Acid, JS–114, JS–101, 126–F, Cantron)
- Cat’s Claw (uncaria tomentosa)
- Coenzyme Q10 (CoQ10, vitamin Q10, ubiquinone, ubidecarenone)
- Coriolus (versicolor, trametes versicolor, Yun Zhi)
- Echinacea
- Essiac
- Fish Oil
- Flower Essence
- Gerson Therapy
- Ginkgo Biloba (maidenhair tree)
- Glucosamine
- Hoxsey Herbal Therapy
- Hydrazine Sulfate (sehydrin)
- Kava (piper methysticum)
- Lorenzo’s Oil
- Milk Thistle (silybum marianum; silymarin)
- Mistletoe (Isca dor®)
- Saw Palmetto
- 714-X
- Shark Cartilage Products
- St. John’s Wort
- Valerian (Valeriana officinalis)
- Yohimbe

**Energy Medicine**

**Acupressure:** Acupressure is an ancient Chinese technique based on the principles of acupuncture, and involves the use of finger pressure, without needles, on specific points along the body. It is a proposed way of accessing and releasing blocked or congested energy centers in the body. Chinese cultures believe the points to be junctures of meridian pathways that carry energy called "chi." Teishin, also called needless acupuncture, is an example of an acupressure therapy.

Clinical trials have been conducted investigating acupressure for various conditions including allergic rhinitis, labor pain, nausea and vomiting, dysmenorrhea, glaucoma, insomnia, and end-stage renal disease. Matthews et al. (2010) conducted a systematic review of randomized controlled trials to assess the safety and effectiveness of various types of interventions for nausea, vomiting and retching in early pregnancy. Of the 27 trials that met inclusion criteria five studies used acupressure. Four of the studies compared P6 acupressure to placebo and there were no statistically significant effects with acupressure.

**Biofield Therapeutics:** Biofield therapeutics, also called energy healing or “laying on of hands” (e.g., healing touch, spiritual touch) is one of the oldest forms of untested healing known to humankind. It involves the transfer of energy from healer to patient and the manipulation of the human body’s energy fields (Jain and Mills, 2010).

**Crystal Healing:** Crystal healing is the belief that certain stones and crystals contain special healing energy that can be transferred into people to provide protection against illness and disease and provide spiritual guidance.
Multiple types of crystals are proposed for healing of all types of conditions and diseases (e.g., amethyst for headaches and balancing blood sugar and aquamarine for heart and immune system problems).

**Cupping:** Cupping uses one of several types of cups (e.g., glass, bamboo) placed on the desired acupoints of the skin to make a local place of hyperemia or hemostasis for the purpose of curing disease (e.g., fibromyalgia, low back pain, urticaria, asthma, cough, herpes zoster). There are several types of cupping including: retained cupping, flash cupping, water cupping, bleeding or wet cupping, moving cupping, needle cupping, medicinal or herbal cupping, and combined cupping (Cao, et al., 2010).

In a systematic review of 135 randomized controlled trials (RCTs) (Cao, et al., 2012) cupping therapy (mainly wet cupping) was used for the treatment of “herpes zoster, facial paralysis (Bell’s palsy), cough and dyspnea, acne, lumbar disc herniation, and cervical spondylitis”. Data on cupping therapy combined with other treatments, such as acupuncture or medications, showed significant benefit (e.g., p<0.00001) over other treatments used alone in the treatment of herpes zoster, acne, facial paralysis, and cervical spondylitis. Despite the number of RCTs included in this analysis, the authors stated that “there remains a lack of well-designed investigations” and 84.4% of the studies were at high risk of bias. Additional limitations of the studies included: lack of blinding, especially of outcome assessors and statistics; lack of reporting of methodology details; and heterogeneity of treatment regimens.

**Gemstone Therapy:** Gemstone therapy is an alternative technique proposed for strengthening the body and resolving issues and patterns. It is based on the theory that gemstones carry vibrational rates and, when placed within a person’s aura, can change the person’s vibrational rates.

**Magnet Therapy:** Magnet therapy is a type of alternative therapy involving static magnetic fields and is claimed to have healing powers. While some claim that magnets can help broken bones heal faster, most proponents advocate that magnets relieve pain.

**Meridian Therapy:** Meridian therapy or the knowledge of meridians, a self-healing system, focuses on maintaining balance between body organs, and emotional and spiritual elements. Reflexologists propose that keeping the body’s vital energies flowing aids the body in self-healing.

**Millimeter Wave Therapy:** Millimeter wave therapy uses low-power millimeter wave (MW) irradiation to treat a variety of conditions ranging from skin diseases and wound healing to various types of cancer, gastrointestinal and cardiovascular diseases and psychiatric illnesses.

**Moxibustion Therapy:** Moxibustion is a variation of acupuncture and involves the application of heat from the burning of the herb moxa (i.e., Artemisia vulgaris or mugwort) at the acupuncture point. Indirect moxibustion involves placing an insulating material (e.g., ginger, salts) between the moxa cone and skin. Moxibustion has been proposed for the treatment of pain, joint soreness (e.g., osteoarthritis) and for other conditions such as hypertension and cancer.

Systematic reviews and meta-analysis of randomized controlled trials have investigated moxibustion for the treatment of osteoarthritis (Choi, et al., 2012), hypertension (Kim, et al., 2010) and ulcerative colitis (Lee, et al., 2010a), for stroke patients to improve motor and/or urinary function during rehabilitation (Lee, et al., 2010b), as well as for the relief of chemotherapy side effects in cancer patients (Lee, et al., 2010c). Due to the limited number of studies with small patient populations, high risk of bias, and low methodological quality moxibustion is not recommended for these indications.

**Qigong Longevity:** Qigong longevity exercise, or qigong, is a component of traditional Chinese medicine that combines movement, meditation and regulation of breathing to enhance the flow of Qi (an ancient term given to what is believed to be vital energy) in the body, improve blood circulation and enhance immune function.

Wang et al. (2012) conducted a systematic review of seven studies to evaluate the effectiveness of qigong exercise on immunity and prevention or treatment of infectious diseases. Two randomized controlled trials, two controlled clinical trials and three retrospective reviews met inclusion criteria. Due to the poor quality of the studies, meta-analyses could not be performed. Studies were heterogeneous in design with varied dosage and quality of qigong exercise, comparison groups and outcome measures. The majority of the studies were conducted on healthy adults and the clinical implications of changes in outcomes measures in healthy adults are
unclear. Likewise, in a systematic review of 23 randomized and non-randomized controlled studies, Chan, et al. (2012) reported that due to the high risk of bias and poor methodology of the studies, conclusive statements could not be made regarding the effectiveness of qigong exercise in cancer care.

**Reiki:** Reiki is a Japanese word representing universal life energy. Reiki is based on the belief that when spiritual energy is channeled through a Reiki practitioner, the patient's spirit is healed, which in turn heals the physical body. VanderVaart et al. (2009) conducted a systematic review to assess the therapeutic effect of Reiki. Twelve studies met inclusion criteria including five randomized controlled trials. Due to the limited number of studies, small patient outcomes, poor study methodology, various outcome measures, and the possibility of bias, a definitive conclusion regarding the effectiveness of Reiki could not be established.

**Therapeutic Touch:** Therapeutic Touch is based on the assumption that the human energy field is abundant and flows in balanced patterns in health but is depleted or unbalanced in illness or injury. Practitioners believe they can restore health by sensing and adjusting such fields.

A Cochrane review of therapeutic touch for healing acute wounds included four randomized or quasi randomized controlled trials (n=132) and concluded that there was no robust data to support the effectiveness of therapeutic touch on this patient population. All trials were at high risk of bias, outcomes which were variable and inconsistent reported either worsening of conditions or no significant difference when touch was used (O'Mathúna, et al., 2012).

**Manipulative and Body-Based Methods**

**Alexander's Technique:** Alexander's technique seeks to rectify learned habits by reteaching the most basic elements of movement, posture and alignment. Practitioners expect improved coordination and balance, ease of movement, greater flexibility, reduction of tension and pain relief as the most basic benefits.

**AMMA Therapy®:** AMMA Therapy, an integration of Oriental medical principles, is a specialized form of massage that focuses on the balance and movement of energy within the body. Hand techniques are used to balance the flow of energy in the channels of the body through which energy passes. The therapist relies on the sensitivity and strength of hand massage and manipulation of the energy movement.

**Colonic Irrigation, Colonic Lavage, Colonic Cleansing:** Colonic irrigation, colonic hydrotherapy, or colonic lavage involves inserting a tube into the rectum and gently flushing it with water. Colonic cleansing involves ingesting a variety of powdered or liquid laxative substances. These methods are proposed for cleansing the colon of waste and toxic materials.

**Craniosacral Therapy:** Craniosacral therapy, also referred to as cranial osteopathy, cranial therapy, bio-cranial therapy, bio cranial stretching, craniopathy, sacro occipital technique, involves intrinsic movements of the bones of the skull which are believed to reveal different rhythmic tidal motions in the body. These movements are measured with scientific instruments and are thought to be a direct expression of the health of the system, linked with physical, mental and emotional health.

**Ear Candling:** Ear candling is accomplished by a process called convection through which softer waxes and toxins are drawn out of the ear, oxidized and turned into vapors during the treatment. High-quality ear candles are hand-made from beeswax and unbleached cotton cloths. These specially fabricated candles are typically 9–12 inches long and will burn for approximately ten minutes.

**Feldenkrais Therapy:** Feldenkrais is a method of exercise therapy designed to improve coordination. It is a bodywork system in which the person is viewed as a complex system of intelligence and function and all movement reflects the state of the nervous system and the individual’s self-awareness.

**Inversion Therapy:** Inversion therapy is proposed to relieve back and neck pain by gently stretching the vertebrae using the person's own body weight by hanging upside down. It is proposed that inversion therapy can relieve back pain, decompress the spine, stretch muscles and ligaments, relieve stress, improve circulation and help maintain overall good health. However, inversion is contraindicated in numerous conditions, including bone weakness, recent fractures, conjunctivitis, glaucoma, heart disorders, hernias and many others.
Myotherapy: Myotherapy is a method of relaxing muscle spasms, improving circulation and alleviating pain. To diffuse trigger points, pressure is applied to the muscle for several seconds by means of fingers, knuckles and elbows. The success of this method is said to depend on the use of specific corrective exercise for the freed muscles.

Neural Therapy: Neural therapy is an injection technique intended to provide instant relief of pain, increased motion and return of function. It relies on anesthetic injections to clear up electrical interference causing problems in the body. The therapy is typically used to treat chronic pain, but proponents say that the people most likely to benefit are those who've failed to respond to chiropractic care, acupuncture, or physical therapy. It is recommended if surgery or nerve block treatments fail.

Pfrimmer Deep Muscle Therapy®: Pfrimmer Deep Muscle Therapy involves working across the muscles to manipulate deep tissues. The goal of treatment is to stimulate circulation and regenerate lymphatic flow to promote detoxification and oxygenation of stagnant tissues.

Pilates: Pilates is an exercise system that focuses on improving body flexibility, strength, and awareness without adding bulk. It involves a series of controlled movements performed on exercise equipment and/or on the floor and resistance training that is proposed to cause spinal cord alignment and build muscle strength.

In a systematic review and meta-analysis of five studies (n=139), Pereira et al. (2012) reported no improvement in functionality or pain with Pilates compared to lumbar stabilization exercises. Lim et al. (2011) conducted a systematic review and meta-analysis of seven randomized controlled trials and analysis of the pooled data showed significant pain relief (p=0.04) with Pilates. However, when Pilates was compared to standard exercises there were no significant differences in pain relief or in disability scores. Studies were limited by small patient populations, short-term follow-ups, possible publication bias, heterogeneity of Pilates and conventional interventions, and poor methodological quality.

Reflexology: Reflexology, or zone therapy, is the study of the reflexes organized around a system of points on the hands and feet that correspond, or reflex, to every part of the body. The theory is that stimulating and applying pressure to the feet or hands increases circulation and promotes specific bodily and muscular functions.

In a systematic review of 23 randomized controlled trials, Ernst et al. (2011) concluded that there was insufficient evidence to support reflexology for the treatment of “any medical condition.” Fourteen studies reported that reflexology was not an effective treatment compared to eight studies that reported positive outcomes. Positive outcomes were reported for the treatment of “diabetes, premenstrual syndrome, cancer patients, multiple sclerosis, symptomatic idiopathic detrusor over-activity and dementia.” Overall, the studies were of poor methodological quality and included heterogeneous patient populations, various outcome measures, various treatment regimens and short-term follow-ups.

Remedial Massage: Remedial massage is the rhythmical kneading and stroking of the body's soft tissues to relieve accumulated tension, restore flexibility to muscles, and offer relief from pain. In addition, holistic massage is proposed to have a calming effect on the neuromuscular system bringing about deep relaxation and restoring energy.

A systematic review and meta-analysis of 34 randomized controlled trials concluded that the evidence did not support infant massage for promoting physical and mental health on low-risk groups of infants under age six months. Available evidence was of poor quality, and many studies did not address the biological plausibility of the outcomes being measured or the mechanisms by which change might be achieved (Bennett, et al., 2013).

Rolfing: Rolfing, or structural integration, is a holistic system of soft-tissue manipulation and movement education that is intended to bring the body's natural structure into proper balance and alignment. The intent is to realign the body structurally and harmonize its fundamental movement patterns to enhance vitality and well-being.

Trager® Bodywork: Trager bodywork is an approach that utilizes gentle, nonintrusive, natural movements to help release deep-seated physical and mental patterns and facilitate deep relaxation, increased physical
mobility, and mental clarity. These patterns may have developed in response to accidents, illnesses, or any kind of physical or emotional trauma, including the stress of everyday life.

**Tui Na:** Tui Na, or Tuina, uses massage and manipulation techniques to establish a more harmonious flow of Qi through the channels and collaterals in the body, allowing natural healing. Methods include the use of hand techniques to massage muscles and tendons, acupressure techniques, and manipulation techniques to realign the musculoskeletal and ligamentous relationships. External herbal poultices, compresses, liniments, and salves are used to enhance the massage and manipulation. Tui Na is proposed for the treatment of musculoskeletal disorders and chronic stress-related disorders of the digestive, respiratory and reproductive systems. Contraindications include conditions involving fractures, phlebitis, infectious conditions, open wounds, and lesions.

**Visceral Massage:** Visceral massage, or visceral manipulation, is massage of the internal muscular viscera proposed to relieve pain anywhere including back, abdomen, legs, as well as relieve migraine headaches. It is also proposed to improve function by relieving postpartum adhesions and adhesions around the lungs, liver, pancreas, kidneys and gall bladder.

**Mind-Body Medicine**

**Art Therapy:** Art therapy is a creative process utilizing art as a healing and life-affirming technique. The term typically applies to the use of the visual arts in psychotherapy to improve a feeling of emotional well-being. Art therapy is used in mental health therapy and other settings to help focus on an individual's creative process, and to enhance their use of leisure as a stress reduction activity.

Wood et al. (2011) conducted a systematic review to assess the available evidence on the effectiveness of art therapy for symptomatic control of patients with cancer. Twelve randomized controlled trials and case series (n=402) met inclusion criteria. The studies showed that art therapy is most frequently used by women with breast cancer. Due to the heterogeneity of the studies, variations in the model and content of the interventions, and various outcome measures no overall effect was determined.

**Bioenergetics’ Analysis:** Bioenergetics’ analysis is a somatic psychotherapy that works with both body and mind to help individuals resolve emotional problems and increase their potential for pleasure and joy in living.

**Chung Moo Doe:** Chung Moo Doe therapy is a martial art that has been practiced for over 1500 years in East Asia under various names. Along with Tai Chi, Chung Moo Doe includes Kung Fu, Ai-Ki-Do/Hap-Ki-Do, Jujitsu, Tae-Kwon-Do, Bagwa Chang, Ship Pal Gae/18 weapons and Samurai Sword. Many martial arts originate in China with only 20–30% coming from other East Asian countries.

Systematic reviews of randomized and nonrandomized controlled trials have evaluated the effectiveness of Tai Chi as a supportive treatment for stroke rehabilitation (n=15 studies) (Ding, 2012), for the treatment of stress, anxiety, depression and mood disturbance (n=3817) (Wang, et al., 2010), and as a therapeutic intervention for the treatment of patients with cardiovascular risk factors or cardiovascular conditions (e.g., coronary artery disease, congestive heart failure) (n=29 studies) (Yeh, et al., 2009). Definitive conclusions were limited due to poor to moderate study quality; possible publication bias; wide variety of Tai Chi styles, frequency, duration and follow-up; inadequate or no controls; combinations of various treatment activities; and heterogeneity of outcome measures.

**Color Therapy:** Color therapy, or chromotherapy, uses energies and sensitivities to color to identify and correct imbalances in body energies. It is proposed that disorders can be healed by applying color through visualization or verbal suggestions.

**Dance Movement Therapy:** Dance movement therapy is the psychotherapeutic use of movement and dance to engage a person creatively in a process believing to further their emotional, cognitive, physical and social integration. It is founded on the principle that movement reflects an individual’s patterns of thinking and feeling.

**Equestrian Therapy:** Equestrian therapy (i.e., horseback riding or hippotherapy) is proposed to offer a person with a disability a means of physical activity that aids in improving balance, posture, coordination, the development of a positive attitude and a sense of accomplishment. Bronson et al. (2010) conducted a systematic review of the literature to evaluate the ability of hippotherapy to improve balance in multiple sclerosis.
patients. Three case series with less than 11 patients each met inclusion criteria. The patients engaged in a mean 7.75 hours of therapy over a mean 11.2 weeks. There is insufficient evidence to support hippotherapy for this indication.

**Faith Healing:** Faith healing is the belief that some people are able to channel divine powers to heal injury and cure disease. Patients who seek the assistance of a faith healer must believe strongly in the healer’s divine gifts and ability to focus on illness.

Following a systematic review of five randomized controlled trials \( n=1130 \), Candy et al. (2012) found “inconclusive evidence” that interventions with spiritual or religious components for adults in the terminal phase of a disease enhanced well-being. Limitations of the studies included: all studies were undertaken in the same country; in the multi-disciplinary palliative care interventions it was unclear if all participants received support from a chaplain or a spiritual counselor; it was unclear whether the participants in the comparative groups received spiritual or religious support, or both, as part of routine care or from elsewhere; and there was a “paucity of quality research”.

**Guided Imagery, Interactive:** Guided imagery promotes the use of imagery to help a patient connect with deeper resources at the cognitive, affective and somatic levels. The guide’s role is to facilitate an enhanced awareness of the unconscious imagery the patient has and train them to work effectively with this imagery on their own behalf.

In a systematic review of 15 randomized controlled trials \( n=1172 \), Posadzki et al. (2012) reported that the evidence for guided imagery for the relief of non-musculoskeletal pain was inconclusive. Overall, the methodology was poor; outcomes were conflicting; and patient populations, study design, outcome measures and types of guided imagery were heterogeneous.

**Hellerwork:** Hellerwork is a form of deep-tissue bodywork designed to realign and rebalance the body, releasing chronic tension and stress and producing a more relaxed, youthful state. The central premise is that a structurally misaligned body experiences gravity as stressful. When movement and flexibility are limited, there is energy loss, aging and deterioration.

**Humor Therapy:** Humor therapy targets laughter as a means to lower blood pressure, reduce stress hormones, increase muscle flexion and boost immune function. It is proposed to raise levels of infection-fighting T-cells, disease-fighting proteins called Gamma-interferon, and B-cells, which produce disease-destroying antibodies. Laughter is also thought to trigger the release of endorphins, the body’s natural painkillers, and to produce a general sense of well-being.

**Hypnosis:** Hypnosis is a psychological condition in which an individual may be induced to show apparent differences in behavior and thinking. It employs techniques to induce states of selective attentional focusing or diffusion combined with enhanced imagery. It is often used to induce relaxation. Hypnosis is recognized as a treatment modality for pain control, weight control, irritable bowel syndrome, and as an adjunct to cognitive behavioral and other therapies. Hypnosis has also been proposed for reducing fear and anxiety, reducing the frequency and severity of headaches, and controlling bleeding and pain during dental procedures. The ACS states that, although there is no scientific evidence that hypnosis can influence the development or progression of cancer, it can help to improve the quality of life for some people with cancer (ACS, 2008).

Systematic reviews and randomized controlled trials have reported that there is insufficient evidence to support hypnosis for pain management during labor and childbirth \( n=1213 \) (Madden, et al., 2012), children \( n=69 \) undergoing dental treatment (Al-Harasi, et al., 2010) and treatment of irritable bowel syndrome \( n=147 \) (Webb, et al., 2007). The authors concluded that the quality of the trials was inadequate to make firm conclusions and in some cases there were no significant differences in outcomes when hypnosis was used.

**Meditation/Transcendental Meditation (TM®):** Meditation/Transcendental Meditation is proposed to be the single most effective technique available for gaining deep relaxation, eliminating stress, promoting health, increasing creativity and intelligence and attaining inner happiness and fulfillment.

**Mirror Box Therapy:** Mirror box therapy is the use of visual illusions created by a mirror and is proposed for the treatment for phantom limb pain, complex regional pain syndrome (CRPS)/reflex sympathetic dystrophy.
syndrome (RSD), stroke, arthritis and carpal tunnel syndrome. Mirror therapy is based on the theory that visual feedback provides a substitute for missing proprioceptive feedback to reduce pain. The limbs are positioned inside a box separated by a mirror. The patient looks into the mirror and sees the image of the unaffected limb, thinking that the affected limb is moving effortlessly. The underlying mechanism accounting for the effectiveness of the therapy has not been established (Thieme, et al., 2012; Moseley, et al., 2008; Selles, et al., 2008).

Systematic reviews and meta-analysis of randomized controlled trials and case series have evaluated box therapy for the treatment of stroke patients, phantom limb pain, complex regional pain syndrome (CRPS), and various upper extremity conditions. For stroke patients, when compared with no treatment, placebo/sham or usual/standard practice, mirror therapy had a significant positive effect on motor function (p<0.0001), pain (p=0.03) and improved activities of daily living (p=0.02). However, the studies were limited by small patient populations, included control interventions that were not routinely used in stroke rehabilitation, and poor methodology. Criteria for which patients would benefit from mirror therapy and how the therapy should be applied have not been established and there is a lack of standardized outcome measures and intervention protocols.

**Music Therapy:** Music therapy includes music sessions for individuals and groups based on client needs. Music therapists assess emotional well-being, physical health, social functioning, communication abilities and cognitive skills through musical responses, using improvisation, receptive listening, song writing, lyric discussion, imagery, performance and learning through music.

In a systematic review of 51 randomized controlled trials (n=3663), Cepeda et al. concluded that listening to music reduced the intensity of pain and opioid requirements, but the “magnitude of the benefits was small and the clinical importance of music was unclear”.

**Primal Therapy:** Primal therapy explores, studies, researches and promotes certain forms of psychotherapy and growth, including those that emphasize uncovering and resolving traumatic experiences. It also aims to develop a community that is congruent with the principles developed from this work.

**Psychodrama:** Psychodrama is a method involving improvisational dramatic action under the guidance of a trained practitioner known as the director. The script is written moment by moment, out of the purposes and concerns of an individual, or the group where the method is being applied. Group members take an active part in the dramas so that they bring it as close to life as possible.

**Yoga:** Yoga is a highly diversified mind-body practice that has evolved into many areas, including fitness training, a system of healing, a purification program, mind-training, a philosophical system, a religious practice or a spiritually-based lifestyle. It typically involves physical postures, breathing techniques, and meditation or relaxation.

Systematic reviews have evaluated peripartum outcomes of yoga, yoga for the prevention of coronary heart disease, treatment of cancer pain and treatment-related side effects, anxiety and stress, and schizophrenia (Babbar, et al., 2012; Bussing, et al., 2012; Harder, et al., 2012; Li, et al., 2012; Vancampfort, et al., 2012). Although some studies suggested improvement in outcomes with yoga, other studies reported that the effectiveness of yoga remained uncertain. Data are conflicting and studies have not been well designed. Large-scale, well designed studies using objective measures and long-term follow-up are needed to draw definitive conclusions regarding the effectiveness of yoga.

**Multi-Therapy Systematic Reviews**
Several systematic reviews have evaluated multiple CAM therapies for the treatment of various conditions including asthma, cancer, depression, diabetes, hypertension, irritable bowel syndrome, pain management, psoriasis, Raynaud’s phenomenon, rheumatoid arthritis, and rhinitis. Although some studies reported clinical improvement with some modalities, overall, the authors agreed that there is insufficient evidence to support CAM for the treatment of these conditions. Studies are limited by small patient populations, minimal and short-term follow-ups, variability in dosage and unknown quality of oral supplements, few evaluations of side effects, inconsistent and inconclusive outcomes, and no controls or comparisons to traditional Western medical therapies.
**Cancer:** Systematic reviews of randomized controlled trials have investigated CAM for the treatment of breast cancer and associated symptoms. Rada et al. (2010) conducted a systematic review of the literature to assess the efficacy of non-hormonal therapies for the treatment of hot flushes in women with a history of breast cancer. Sixteen randomized controlled trials met inclusion criteria and included relaxation therapy (n=2 studies), homeopathy (n=2 studies) and vitamin E (n=1 study). The vitamin E study reported no beneficial effects and one study on relaxation therapy showed significant beneficial effects. Homeopathy did not lead to any differences in number and severity of the hot flushes. Data on continuous outcomes were inconsistent.

Guo et al. (2012) conducted a systematic review including 20 randomized controlled trials (n=1304) that compared Chinese herbal medicine with chemotherapy to chemotherapy alone for the treatment of advanced colorectal cancer. The review showed that some of the herbal medicines in combination with chemotherapy improved 1-year (Jianpi Jiedu formula, Xiaozheng formula and YiqiHuoxue herbal medicine) and 3-year survival (Xiaozheng Formula). Ten out of 13 herbal medicines improved quality of life, and some herbal medicines relieved adverse effects of chemotherapy. However, the methodological quality of most of the studies was poor, and the "beneficial effects might be potentially exaggerated". The analysis showed that "the benefits of herbal medicines for advanced colorectal cancer have not been confirmed".

Another systematic review evaluated the use of Chinese herbs (e.g., shenmai, pishentang) for the treatment of chemotherapy side effects in women with breast cancer (n=542 patients) (Zhang, et al., 2007). Bardia et al. (2006) included acupuncture, support groups, hypnosis, relaxation/imagery, herbal supplements, music therapy, healing touch, and massage therapy (N=1499 patients) for the relief of cancer pain. Ernst et al. (November–December 2006) also reviewed CAM for the treatment of breast cancer pain (n=15 studies) including "psychosocial support, herbal medicine, thymus extract, transfer factor, melatonin, and factor AF2 (xenogenic peptides)". Due to the poor quality of the trials (e.g., small patient population without sample size justification, short-term follow-up, lack of statistical comparison, poor definition of outcomes, and lack of control group), none of these therapies could be recommended for pain relief in cancer patients.

**Depression, Anxiety and/or Sleep Disorders:** Lakhan and Vieira (2010) conducted a systematic review to evaluate the effectiveness of herbs and dietary supplements for the treatment of anxiety and related symptoms. Twenty-one randomized controlled trials and three open-label, uncontrolled observational studies (n=2619) met inclusion criteria. A total of 1786 patients had a diagnosis of depression or anxiety disorder and 877 were healthy volunteers with anxiety related to acute conditions/situations. The authors concluded that nutritional and herbal supplements were an effective method for the treatment of anxiety but also stated that the positive effects could be due to a placebo effect. Extracts of passionflower or kava and combinations of L-lysine and L-arginine may be treatment options for anxiety symptoms and disorders, but additional studies are needed to evaluate magnesium-containing and other herbal combinations. There was in sufficient evidence to support St. John’s wort for the treatment of anxiety. Due to the heterogeneity of the studies and the small patient populations, meta-analysis was not possible.

In a systematic review of randomized controlled trials, Morgan and Jorm (2008) investigated multiple CAM therapies for the treatment of depression including: herbal remedies or dietary supplements (i.e., borage, carnitine/acetyl-L-carnitine, chromium, ginkgo biloba, Korean ginseng, Panax ginseng, lavender, lecithin, melatonin, omega 3 fatty acids, fish oil, S-Adenosylmethionine [SAMe], saffron/coccus sativus L, selenium, St. John’s wort), vitamins (i.e., B1, B12, C, D, and multivitamins), folate, caffeine, autogenic training, bibliotherapy, computerized interventions, distraction, meditation, relaxation training, humor, Qigong, Tai Chi, yoga, aromatherapy, hydrotherapy, light therapy, music, and negative air ionization. There was limited to no evidence on these therapies, as well as inconsistent reporting of active ingredients and mechanisms, ideal dosages, side effects and safety issues for herbs and dietary supplements. Some therapies resulted in immediate but not sustained benefit, and tools for measuring outcomes were inconsistent and/or not well defined. Other limitations included small patient populations, short duration, and minimal or no follow-up.

Additional systematic reviews of randomized and nonrandomized controlled trials have investigated CAM for the treatment of depression, anxiety and/or sleep disturbances. Therapies included yoga, meditation, relaxation, music, various herbs and vitamin supplements, Tai Chi, and Qigong (n=33 randomized controlled trials) (Meeks, et al., 2007), St. John’s wort, homeopathy, relaxation training, music therapy, aromatherapy massage, and yoga (n=19 studies) (Thachil, et al., 2007). Although some studies reported a therapeutic effect following a CAM intervention (e.g., Tai Chi, relaxation techniques, and music for sleep disturbances and acupressure for sleep and anxiety), the studies had methodological limitations (e.g., small patient populations, lack of use of
systematic psychiatric diagnoses, loss to follow-up, inadequate controls, and lack of inclusion/exclusion criteria and assessment and reporting of CAM side effects). There is insufficient evidence to support the safety and effectiveness of CAM for the treatment of depression.

**Pain Management:** A systematic review of data from five randomized controlled trials (n=326) compared manual healing methods (i.e., massage, reflexology and music) to standard care, no treatment, other non-pharmacological forms of pain management in labor or placebo. The outcome data indicated that massage might have a role in reducing pain and improving a women’s emotional experience during labor but further research is needed due to the small patient populations and heterogeneity of outcome measures (Smith, et al., 2012).

Smith et al. (2006) conducted a systematic review and meta-analysis of 14 randomized controlled trials (n=1537) that compared complementary and alternative medicine (i.e., three acupuncture trials, one audio-analgesia trial, two acupressure trials, one aromatherapy trial, one massage trial, one relaxation trial, and five hypnosis trials) to placebo, no treatment or pharmacotherapy for pain management in labor. Acupuncture and self-hypnosis decreased the need for pain relief and requirements for pharmacotherapy, respectively. There was insufficient evidence to support the effectiveness of the other therapies. With the exception of the acupuncture and hypnosis trials, the authors noted that the number of women studied was small, and few complementary therapies had “been subjected to proper scientific study.”

**Psoriasis:** Smith et al. (2009) conducted a systematic review of randomized controlled trials to identify the evidence-based information about CAM for the treatment of psoriasis. The studies were categorized as either vitamins/herbs/minerals, fish oil, climatotherapy, acupuncture/Chinese medicine, and mind/body. The vitamins, herbs and minerals category included studies on vitamin D, inositol, zinc, selenium, neem, aloe vera, vitamin B12 with avocado oil, mahonia aquifolium (i.e., bayberry or Oregon grape), and oleum horwathiensis. The authors concluded that due to the low quality of the studies and conflicting results, additional studies are needed to establish the safety and efficacy of these modalities before recommendations for CAM for the treatment of psoriasis can be made. There is also the potential risk of side effects from aloe vera, Chinese medicine and climatotherapy, such as allergic contact dermatitis, hepatotoxicity, and increased risk for skin cancer, respectively.

**Rhinitis and Asthma:** A systematic review by Passalacqua et al. (2006) on CAM for the treatment of rhinitis and asthma included randomized controlled trials (n=57) involving acupuncture, herbal medicines, homeopathy, breathing techniques, yoga, and chiropractic-spinal manipulation. The authors concluded that from a scientific viewpoint, there was no “definitive or convincing proof of efficacy” for the use of CAM in rhinitis or asthma, and there was an absence of quantitative measures in the studies. Therefore, it was not possible to provide evidence-based recommendations for the use of these modalities.

**Professional Societies/Organizations**

**American Academy of Allergy, Asthma & Immunology (AAAAI):** In their clinical review of CAM (Mainardi, et al., 2009) which included vitamins D, E, C and A, magnolol, quercetin, resveratrol, ma huang (ephedrine sinica), Ayurvedic medicine, Kampo medicine for the treatment of asthma, atopic dermatitis, and allergic rhinitis, the AAAAI concluded that further studies are needed using “larger sample sizes, longer study durations, comparable absolute measures, and well-constructed study designs that control for biases”. They also stated that the following are unknown: “the true efficacy and safety of CAM therapies, the efficacy of CAM therapies alone (as alternatives) in the treatment of various disorders, the individual CAM therapeutic mechanism of effects (some may be multiple), the active component of individual CAM therapies, the potential drug-drug and drug-herb-phytochemical and vitamin interactions”.

**American Academy of Pediatrics (AAP):** The 2008 AAP Task Force on Complementary and Alternative Medicine, the Provisional Section on Complementary, Holistic, and Integrative Medicine (Kemper, et al., 2008) published guidance on the use of CAM in pediatrics. The Task Force concluded that pediatricians and other clinicians who care for children have the responsibility to advice and counsel patients about relevant, safe, effective, and age-appropriate health therapies including CAM and should routinely inquire as to whether or not the patient is using any specific CAM therapies. They advised the clinician to work with the parents to consider and evaluate all appropriate treatments and monitor the patient’s response to treatments. They also stated that the physician should be knowledgeable about CAM therapies and evidence-based information.
In guidelines for the management of autism spectrum disorders (ASDs), the AAP (Myers, et al., 2007) stated that CAM therapies used to treat ASDs have included “immunoregulatory interventions (e.g., dietary restriction of food allergens, administration of immunoglobulin or antiviral agents), detoxification therapies (e.g., chelation), gastrointestinal treatments (e.g., digestive enzymes, antifungal agents, probiotics, “yeast-free diet,” gluten/casein-free diet), and dietary supplement regimens (e.g., vitamin A, vitamin C, vitamin B-6, magnesium, folic acid, folinic acid, vitamin B-12, dimethylglycine, trimethylglycine, carnosine, omega-3 fatty acids, inositol, various minerals),” “auditory integration training, behavioral optometry, craniosacral manipulation, dolphin-assisted therapy, music therapy and facilitated communication”. AAP noted that many CAM therapies have been inadequately evaluated because of “methodologic flaws, insufficient numbers of patients or lack of replication” and cannot be recommended. Appropriately designed trials have demonstrated no significant benefit from the use of dimethylglycine (an amino acid), vitamin B-6 and magnesium, auditory integration training, omega-3 fatty acids, and gluten/casein-free diet.

American Cancer Society (ACS): In their operational statement on CAM methods for cancer management, the ACS (2014) urged patients who are thinking about using complementary or non-mainstream therapies to discuss them with their health care team first. As noted above in the background, there are many CAM modalities that the ACS recognizes as being ineffective and/or unproven for the treatment of various types of cancer. ACS also stated that the use of CAM can delay mainstream medical treatment allowing the cancer to grow and spread. Some CAM therapies have been associated with serious problems and death.

American College of Chest Physicians (ACCP): The ACCP (Deng, et al., 2013) published evidence-based clinical practice guidelines on complementary therapies and integrative medicine and suggested that mind-body modalities could be used as part of a multidisciplinary approach to treating the symptoms of cancer-related pain, nausea and vomiting associated with chemotherapy, anxiety, and sleep and mood disturbances. Yoga and massage therapy may be beneficial in reducing fatigue, anxiety and/or pain.

American College of Rheumatology (ACR): The ACR (2012) position statement on complementary and alternative medicine for rheumatic diseases supports the integration of CAM modalities “proven to be safe and effective by scientifically rigorous clinical trials published in the biomedical peer review literature” and advised caution in using those therapies not scientifically studied. For interventions for which randomized controlled trials are not feasible, “innovative methods of evaluation are needed, as are measures and standards for the generation and interpretation of evidence.”

American Psychiatric Association: The American Psychiatric Association’s Task Force on Complementary and Alternative Medicine (Freeman, et al., 2010) conducted a systematic review of randomized controlled trials to evaluate the evidence on commonly used CAM therapies for the treatment of major depressive disorder (MDD). Therapies included omega-3 fatty acids, St. John’s wort (Hypericum), folate, S-adenosyl-L-methionine (SAMe), bright light therapy, exercise, and mindfulness psychotherapies (i.e., mindfulness-based cognitive therapy, problem-solving therapy, well-being therapy). The Task Force concluded that although some CAM therapies were promising, “more rigorous studies” to determine their role in the treatment of MDD was necessary. It was noted that the “greatest risk of pursuing a CAM therapy is the possible delay of other well-established treatments.”

National Cancer Institute (NCI): NCI (2013) stated that cancer patients using or considering complementary or alternative therapy should discuss this decision with their health care provider to ensure coordination of care. “Some complementary and alternative therapies may interfere with standard treatment or may be harmful when used with conventional treatment. It is also a good idea to become informed about the therapy, including whether the results of scientific studies support the claims that are made for it.”

National Comprehensive Cancer Network® (NCCN®): In their Clinical Practice Guidelines in Oncology™, NCCN (2014a) stated that complementary therapies including massage therapy, yoga, muscle relaxation, and stress reduction based on mindfulness have been evaluated in some studies and the data suggested that these therapies might be effective in reducing fatigue in cancer patients.” NCCN (2014b) listed imagery, hypnosis, distraction training, and relaxation training as nonpharmacological interventions for the treatment of adult cancer pain. Relaxation/systemic desensitization, hypnosis/guided imagery and music therapy are noted as interventions for anticipatory nausea and vomiting (NCCN, 2014c).
Society for Integrative Oncology (SIO): The SIO (Deng, et al., 2009) evidence-based practice guidelines included a systematic review of complementary therapy and botanicals in the care of cancer patients. Mind-body modalities, bioenergy field therapy, and dietary supplements were evaluated. The SIO stated that study results varied and overall, the clinical role of these therapies has not been established.

Outside the United States
Many complementary and alternative modalities are practiced all over the world. For example, Ovamed GmbH (Barsbuttel, Germany) specializes in the development of treatments using biological organisms and distributes Tricuris suis ova (TSO) in Europe in pill form. Coronado Biosciences, Inc. (Burlington, MA) has acquired the rights to distribute TSO in South America and Japan.

National Institute for Clinical Excellence (NICE): NICE (United Kingdom) (2008) published a guideline document on the treatment of irritable bowel syndrome (IBS) in adults. The review included the use of homeopathic medicine, Chinese herbal medicine and reflexology. Regarding homeopathy for IBS, NICE stated that randomized trials for the past 30 years were found. Only one quasi-randomized trial was found regarding the use of reflexology for the treatment of IBS (n=34). Six trials met inclusion criteria for evaluation of the use of Chinese herbal medicines. The studies utilized various combinations of herbal preparations. The Guideline development group (GDG) concluded that “the review of evidence suggests that some herbal preparations may be clinically effective in people with IBS and are well tolerated. However, the GDG believed there were too many uncertainties regarding type and dose of herbal medicines to make a recommendation for practice, and proposed that these interventions should be investigated further in a research recommendation.”

New Zealand Guidelines Group: In a mental health disorders guideline for the management of depression, The New Zealand Guidelines Group (2008) conducted a systematic review of randomized controlled trials of therapies used for the treatment of depression in adults in primary care. The authors stated that “there was insufficient evidence to determine whether any complementary or alternative medicines are effective for the treatment of depression in young people.” Very few randomized controlled trials were found and none were found for the use of St. John’s Wort for depression in young people. The Groups also pointed out that due to safety concerns, patients using St. John’s wort should be advised of possible drug interactions. One small study (n=28) supported the possibility that omega-3 supplements may be effective in the treatment of childhood depression and it is proposed that omega-3 may be useful in the treatment of women in antenatal or postnatal periods, but no controlled trials were available.

Royal Australian and New Zealand College of Obstetrician and Gynecologists (RANZCOG): In their statement on the use of vitamin and mineral supplements during pregnancy, the RANZCOG (2013) stated that there is a lack of high quality evidence to support the use of omega-3 fatty acid supplements during pregnancy.

Summary
Complementary and alternative medicine (CAM) encompasses a wide array of practices and treatment modalities that deviate from conventional Western medical treatment. They may be used in lieu of, or in conjunction with, traditional medical therapies. Overall, randomized controlled trials included heterogeneous small patient populations; short-term follow-ups; various controls, treatment regimens and outcome measures; inconsistent and conflicting outcomes; and poor methodology. Some CAM testing methods and therapies/treatments lack standardization of regimens and/or practitioner training. Systematic reviews have been unable to make firm conclusions about CAM testing methods and therapies due to the study limitations and in some cases, lack of data. The evidence in the published peer-reviewed scientific literature does not support the safety, efficacy and/or clinical utility of the diagnostic testing and therapies discussed within the scope of this Coverage Policy.

Coding/Billing Information

Note: 1) This list of codes may not be all-inclusive.
     2) Deleted codes and codes which are not effective at the time the service is rendered may not be eligible for reimbursement.

Chemical Hair Analysis
Experimental/Investigational/Unproven/Not Covered when used to report chemical hair analysis:

<table>
<thead>
<tr>
<th>CPT® Codes</th>
<th>Description</th>
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</thead>
<tbody>
<tr>
<td>80178</td>
<td>Lithium</td>
</tr>
<tr>
<td>82108</td>
<td>Aluminum</td>
</tr>
<tr>
<td>82175</td>
<td>Arsenic</td>
</tr>
<tr>
<td>82300</td>
<td>Cadmium</td>
</tr>
<tr>
<td>82310</td>
<td>Calcium; total</td>
</tr>
<tr>
<td>82525</td>
<td>Copper</td>
</tr>
<tr>
<td>83018</td>
<td>Heavy metal (eg, arsenic, barium, beryllium, bismuth, antimony, mercury); quantitative, each</td>
</tr>
<tr>
<td>83540</td>
<td>Iron</td>
</tr>
<tr>
<td>83655</td>
<td>Lead</td>
</tr>
<tr>
<td>83735</td>
<td>Magnesium</td>
</tr>
<tr>
<td>83785</td>
<td>Manganese</td>
</tr>
<tr>
<td>83825</td>
<td>Mercury, quantitative</td>
</tr>
<tr>
<td>83885</td>
<td>Nickel</td>
</tr>
<tr>
<td>83925</td>
<td>Opiate(s), drug and metabolites, each procedure</td>
</tr>
<tr>
<td>84100</td>
<td>Phosphorus inorganic (phosphate)</td>
</tr>
<tr>
<td>84255</td>
<td>Selenium</td>
</tr>
<tr>
<td>84302</td>
<td>Sodium; other source</td>
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</table>

<table>
<thead>
<tr>
<th>HCPCS Codes</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>P2031</td>
<td>Hair analysis (excluding arsenic)</td>
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Salivary Hormone Panel
Experimental/Investigational/Unproven/Not Covered when used to report a salivary hormone panel:

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<tr>
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<th>Description</th>
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<tbody>
<tr>
<td>80420</td>
<td>Dexamethasone suppression panel, 48 hour This panel must include the following: Free cortisol, urine (82530 x 2), Cortisol (82533 x 2), Volume measurement for timed collection (81050 x 2)</td>
</tr>
<tr>
<td>80426</td>
<td>Gonadotropin releasing hormone stimulation panel This panel must include the following: Follicle stimulating hormone (FSH) (83001 x 4), Luteinizing hormone (LH) (83002 x 4)</td>
</tr>
<tr>
<td>82157</td>
<td>Androstenedione</td>
</tr>
<tr>
<td>82530</td>
<td>Cortisol; free</td>
</tr>
<tr>
<td>82533</td>
<td>Cortisol; total</td>
</tr>
<tr>
<td>82626</td>
<td>Dehydroepiandrosterone (DHEA)</td>
</tr>
<tr>
<td>82627</td>
<td>Dehydroepiandrosterone–sulfate (DHEA-S)</td>
</tr>
<tr>
<td>82670</td>
<td>Estradiol</td>
</tr>
<tr>
<td>82677</td>
<td>Estradiol</td>
</tr>
<tr>
<td>82679</td>
<td>Estrone</td>
</tr>
<tr>
<td>82784</td>
<td>Gammaglobulin (immunoglobulin); IgA, IgD, IgG, IgM, each</td>
</tr>
<tr>
<td>82787</td>
<td>Gammaglobulin (immunoglobulin); immunoglobulin subclasses (eg, IgG1, 2, 3, or 4), each</td>
</tr>
<tr>
<td>83001</td>
<td>Gonadotropin; follicle stimulating hormone (FSH)</td>
</tr>
<tr>
<td>83002</td>
<td>Gonadotropin; luteinizing hormone (LH)</td>
</tr>
<tr>
<td>83498</td>
<td>Hydroxyprogesterone, 17-d</td>
</tr>
<tr>
<td>84144</td>
<td>Progesterone</td>
</tr>
<tr>
<td>84234</td>
<td>Receptor assay; progesterone</td>
</tr>
<tr>
<td>84402</td>
<td>Testosterone, free</td>
</tr>
<tr>
<td>84403</td>
<td>Testosterone, total</td>
</tr>
<tr>
<td>HCPCS Codes</td>
<td>Description</td>
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<tr>
<td>-------------</td>
<td>-------------</td>
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<tr>
<td>S3650</td>
<td>Saliva test, hormone level; during menopause</td>
</tr>
<tr>
<td>S3652</td>
<td>Saliva test, hormone level; to assess preterm labor risk</td>
</tr>
</tbody>
</table>

**Fecal Bacteriotherapy, Hypnotherapy, Vitamin Therapy, Activity Therapy, Laetrile, Cellular Therapy, Equestrian/Hippotherapy, Pilates, Yoga:**

**Experimental/Investigational/Unproven/Not Covered:**

<table>
<thead>
<tr>
<th>CPT® Codes</th>
<th>Description</th>
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</thead>
<tbody>
<tr>
<td>44705</td>
<td>Preparation of fecal microbiota for instillation, including assessment of donor specimen</td>
</tr>
<tr>
<td>90880</td>
<td>Hypnotherapy</td>
</tr>
</tbody>
</table>

**HCPCS Codes**

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<tr>
<th>HCPCS Codes</th>
<th>Description</th>
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</thead>
<tbody>
<tr>
<td>A9152</td>
<td>Single vitamin/mineral/trace element, oral, per dose, not otherwise specified</td>
</tr>
<tr>
<td>A9153</td>
<td>Multiple vitamins, with or without minerals and trace elements, oral, per dose, not otherwise specified</td>
</tr>
<tr>
<td>G0176</td>
<td>Activity therapy, such as music, dance, art or play therapies not for recreation, related to the care and treatment of patient’s disabling mental health problems, per session (45 minutes or more).</td>
</tr>
<tr>
<td>G0455</td>
<td>Preparation with instillation of fecal microbiota by any method, including assessment of donor specimen</td>
</tr>
<tr>
<td>J3570</td>
<td>Laetrile, amygdalin, vitamin B 17</td>
</tr>
<tr>
<td>M0075</td>
<td>Cellular therapy</td>
</tr>
<tr>
<td>S8940</td>
<td>Equestrian/hippotherapy, per session</td>
</tr>
<tr>
<td>S9451</td>
<td>Exercise classes, non-physician provider, per session</td>
</tr>
</tbody>
</table>

**Other Complementary and Alternative Medicine Diagnostic Testing and Therapies**

**Experimental/Investigational/Unproven/Not Covered when used to report any complementary or alternative medicine diagnostic testing methods, systems, therapies or treatments listed in this Coverage Policy:**

<table>
<thead>
<tr>
<th>CPT® Codes</th>
<th>Description</th>
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<tbody>
<tr>
<td>86353</td>
<td>Lymphocyte transformation, mitogen (phytomitogen) or antigen induced blastogenesis</td>
</tr>
<tr>
<td>86849</td>
<td>Unlisted immunology procedure</td>
</tr>
<tr>
<td>96379</td>
<td>Unlisted therapeutic, prophylactic, or diagnostic intravenous or intra-arterial injection or infusion</td>
</tr>
<tr>
<td>97039</td>
<td>Unlisted modality (specify type and time if constant attendance)</td>
</tr>
<tr>
<td>97139</td>
<td>Unlisted therapeutic procedure (specify)</td>
</tr>
<tr>
<td>97799</td>
<td>Unlisted physical medicine/rehabilitation service or procedure</td>
</tr>
<tr>
<td>99199</td>
<td>Unlisted special service, procedure or report</td>
</tr>
</tbody>
</table>


107. Sawitzke AD, Shi H, Finco MF, Dunlop DD, Harris CL, Singer NG, Bradley JD, Silver D, Jackson CG, Lane NE, Oddis CV, Wolfe F, Lisse J, Furst DE, Bingham CO, Reda DJ, Moskowitz RW, Williams HJ, Clegg DO. Clinical efficacy and safety of glucosamine, chondroitin sulphate, their combination,
celecoxib or placebo taken to treat osteoarthritis of the knee: 2-year results from GAIT. Ann Rheum Dis. 2010 Aug;69(8):1459-64.


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