



Medical Coverage Policy

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Complementary and Alternative Medicine

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INSTRUCTIONS FOR USE

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Overview

This Coverage Policy addresses complementary and alternative medicine diagnostic testing methods, systems, therapies and treatments that are proposed to reduce disease-based clinical symptoms and improve health and wellness.

Coverage Policy

Coverage for complementary and alternative testing and therapies varies across plans. Please refer to the customer's benefit plan document for coverage details.

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

Each of the following complementary or alternative medicine diagnostic testing methods, systems, therapies or treatments is considered experimental, investigational or unproven:

- **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
 - hydrogen peroxide, intravenous
 - immunoenhancement therapy
 - Kelley-Gonzales therapy
 - Laetrile
 - megavitamin therapy
 - MTH-68
 - ozone therapy
 - Revisi's Guided Chemotherapy
 - Trichuris suis ova therapy
 - over-the-counter biologics (e.g., glucosamine, coenzyme Q10, fish oil [omega-3 fatty acids])

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

- **Manipulative and body-based methods**

- Alexander's technique
- AMMA Therapy®
- Bio Photonic Lymphatic Drainage Treatment (BELD)
- 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
- Martial Arts including Chung Moo Doe therapy
- 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
- outdoor youth programs
- pet therapy
- primal therapy
- psychodrama
- recreational therapy
- wilderness therapy
- yoga

Prescription medications are 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 (NCCAM, 2016). 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, also referred to as natural products, 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.

Some CAM therapies are supported by some degree of scientific evidence, but most of the other CAM therapies lack data in the peer-reviewed published evidence supporting the safety and efficacy of these therapies for specific conditions and are not yet considered an established treatment option.

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; updated 2019).

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, herbals, 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 had 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 had 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.

Diagnostic Testing Methods

Applied Kinesiology (AK): AK is a form of diagnostic testing that uses muscle testing as a type of 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. Available scientific evidence does not support claims that the Greek Cancer Cure is effective in preventing, detecting, or treating cancer.

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 within 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 Post- and PeriMenopausal 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, 2019).

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, estrogens, dihydrotestosterone (DHT) and testosterone. The Expanded Male Hormone Panel™ (eMHP™) includes the seven hormones plus follicle stimulating hormone (FSH) and luteinizing hormone (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 five 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), total secretory IgA (SigA), and wheat gluten sigA 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 and as a bone marker, Pylilinks-D 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.

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 (reaffirmed 2018) 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.

A Cochrane systematic review (Hawke, et al., 2018) of randomized controlled trials investigating oral homeopathic medicinal products for the prevention and treatment of acute respiratory tract infections in children (age <16 years) concluded that the evidence did not show any benefit of homeopathic medicinal products compared to placebo. Eight randomized controlled trials (n=1562) met inclusion criteria. Limitations of the studies included: methodological inconsistencies, high attrition rates, selective reporting, protocol deviations and unclear or high risk of bias. Methodological inconsistencies and significant clinical and statistical heterogeneity precluded robust quantitative meta-analysis.

Banerjee et al. (2017) conducted a systematic review of randomized controlled trials evaluating homeopathy for allergic rhinitis. Eleven studies (n=1654) met inclusion criteria and ten were placebo-controlled trials. Six trials used isopathy (i.e., the causal agent is used for the cure), but they were unsuitable for meta-analysis due to problems of heterogeneity and data extraction. Patient populations ranged from 34–142. Due to the high level of heterogeneity across studies in terms of medical condition and outcome measures and the poor quality of results reported, only three studies could be used for meta-analysis. Meta-analysis of the three studies using *Galphimia glauca* showed that relief of nasal and ocular symptoms favored homeopathy. A homeopathic and a conventional nasal spray produced equivalent improvements in nasal and ocular symptoms. Due to the overall low or uncertain quality of the evidence firm conclusions could not be drawn about the clinical benefit of homeopathy medicine for the treatment of allergic rhinitis.

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. The clinical utility of macrobiotics has not been established.

Naprapathy: Naprapathy or naprapathic medicine is a system that employs 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. Naprapaths are connective tissue specialists who propose to have a specialized, holistic approach to address connective tissue problems (American Naprapathic Association, 2020).

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.

Cochrane systematic reviews of randomized or quasi-randomized controlled trials have reported on the effects of Chinese herbal medicine (CHM) for various conditions including the treatment of subfertile women with polycystic ovarian syndrome (Zhou, et al., 2016). Analysis of five studies (n=414) revealed that there is insufficient evidence to support the use of CHM for women with this syndrome and subfertility. No data were available on live births, and there was no consistent evidence to indicate that CHM influenced fertility outcomes.

The effectiveness of Chinese herbal medicine (CHM) for relief of menopausal symptoms in women over 18 years of age was reviewed by Zhu et al. (2016) in this Cochrane review. Twenty-two randomized controlled trials (n=2902) met inclusion criteria. CHM was compared to placebo, hormone therapy (HT), pharmaceutical drugs, acupuncture, or another CHM formula. There was insufficient evidence that CHMs were any more or less effective than placebo or HT for the relief of vasomotor symptoms. Effects on safety were inconclusive. The quality of the evidence ranged from very low to moderate. Li et al. (2016) reported that analysis of nine randomized controlled trials (n=861) showed limited evidence to assess the effectiveness of CHM for unexplained recurrent miscarriage. No data were available to assess the safety of the intervention for the mother or her baby. There were no data relating to any of the secondary outcomes including obstetrical and other complications for the mother, infant death, perinatal complications and congenital malformations.

Chen et al. (2016) assessed the efficacy and possible adverse effects of the addition of Chinese herbal medicine to treatment with radiotherapy or chemotherapy for esophageal cancer. Nine randomized controlled trials (n=490) were included in this Cochrane review and the authors found no evidence to determine whether traditional Chinese medicine (TCM) was an effective treatment for esophageal cancer. The effect of TCM on short-term therapeutic effects was uncertain.

Two Cochrane systematic reviews of randomized or quasi-randomized controlled trials reported on the effects of Chinese herbal medicine (CHM) for the treatment of 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. 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. The National Cancer Institute (NCI) (2019) stated that antineoplastons are an experimental cancer therapy proposed to provide a natural biochemical substance that is lacking in the body in people with cancer. According to NCI (2019), no randomized controlled trials showing the effectiveness of antineoplastons have been published in the peer-reviewed scientific literature.

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, sicca cell 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.

Zhang et al. (2017) conducted a systematic review and meta-analysis to evaluate the safety and efficacy of cellular therapy for the treatment of diabetic foot ulcer. Six randomized controlled trials (n=241) met inclusion criteria. Outcomes included ankle-brachial index (ABI), amputation-free survival (AFS), transcutaneous oxygen tension pressure (TcPO₂), ulcer healing rate at 12 to 24 weeks post transplantation, pain scales and adverse events. Two studies used mesenchymal stem cells from bone marrow or umbilical cord, three used mononuclear cells (MNCs) from bone marrow or peripheral blood, and one study used bone marrow-derived mesenchymal stem cells (BMSCs) and bone marrow-derived MNCs (BMNCs). The outcomes revealed that significant improvements were seen in the ABI (five studies), TcPO₂ (three studies), pain scores (three studies), AFC (four studies) and ulcer healing rate (three studies). No serious complications were reported. Limitations of the studies include: the limited number of studies, small patient populations (n=6-74), short-term follow-ups (12-24 weeks), heterogeneity of cells used, variability of measurements and criterion of ulcer healing and baseline ulcer conditions that would affect outcomes were not reported in some studies, and lack of information on allocation concealment.

Chahla et al. (2016) conducted a systematic review to assess the safety and efficacy of cellular therapy as an intra-articular injection of the knee for the treatment of osteoarthritis (n=124 knees) and focal cartilage defects (n=176 knees). Four randomized controlled trials without blinding, one prospective cohort study, and one retrospective therapeutic case-control study met inclusion criteria. Although some of the data suggested modest improvement, a placebo effect could not be disregarded. The overall quality of the literature was poor and the methodological quality was fair. The data did not support cellular therapy for these indications.

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 serratia 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 systematic toxicities (Patyar, et al., 2010).

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.

Immunoaugmentative 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. According to NCI (2017, updated 2019), Laetrile/Amygdalin is not approved for use in the United States and has shown little anticancer activity in animal studies and no anticancer activity in human clinical trials. NCI notes that inappropriate advertisement of laetrile as a cancer treatment has resulted in a U.S. Food and Drug Administration investigation that culminated in charges and conviction of one distributor.

Milazzo and Horneber (2015) conducted a Cochrane systematic review of the literature to assess the proposed anti-cancer effect and adverse effects of laetrile and amygdalin. Sixty-nine randomized controlled trials (RCTs) and quasi-RCTs were identified but none met the inclusion criteria. Therefore, beneficial effects of laetrile for cancer patients could not be recommended. According to the authors, there is a considerable risk of serious adverse effects from cyanide poisoning after laetrile, especially after oral ingestion. The risk-benefit balance of laetrile or amygdalin as a treatment for cancer is therefore unambiguously negative.

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. An example of megavitamin therapy is the Myers' Cocktail, which is the intravenous infusion of a combination of Vitamins B1, B2, B3, B5, B6, B12, Vitamin C, magnesium and calcium. The solution is proposed for the treatment of fatigue, fibromyalgia, migraines, allergies and many other conditions (Ali, et al., 2009). There is a lack of evidence that megavitamin therapy improves health outcomes.

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, 2018).

Ozone Therapy: Ozone therapy also known as oxygen therapies or oxidative therapies. The delivery method of ozone traditionally takes one of three forms: gaseous ozone exposure within a hyperbaric chamber, ozonated oils, and ozonated water. Ozone therapies include the following: 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 but scientific evidence supporting this claim is lacking. Ozone therapy has been proposed for the treatment of various conditions including painful temporomandibular joint (TMJ) disorder (TMD), diabetic foot ulcers, acute back pain, lumbar disc herniation, back pain, and hearing loss. However, there is insufficient evidence to support the clinical benefit of ozone therapy.

Fitzpatrick et al. (2018) conducted a systematic review and meta-analysis of randomized controlled trials to evaluate the safety and efficacy of ozone therapy for the treatment of chronic wounds. Nine studies (n=453) met inclusion criteria and investigated the use of ozone therapy in the topical treatment of chronic wounds (e.g., war wounds, burns, and non-healing diabetes, venous, or arterial ulcers). Primary outcomes included: the number of ulcers completely healed, change in wound size, presence or absence of biomarkers in favor of healing, and for diabetic foot ulcers the general appearance of the wound as assessed by Wagner's ulcer classification scale. Secondary outcomes included the complications of pain, toxicity, amputation, infection, and developed pathologies. Meta-analysis revealed a significant (p<0.05) improvement in wound closure (wound healing and

percent wound closure). However, there was no conclusive evidence that ozone therapy was superior to standard treatments. No adverse events from the ozone therapy were reported. Limitations of the studies include: heterogeneous small patient populations; heterogeneity of the treatment regimen (e.g. ozone concentration, treatment duration, frequency of treatment) and type of wounds; and moderate to high risk of bias in the majority of studies. Due to the heterogeneity of the studies firm conclusions could not be made regarding the effectiveness of ozone therapy for the treatment of chronic wounds.

Li et al. (2018) conducted a systematic review and meta-analysis to investigate the safety and efficacy of intra-articular hyaluronic acid (HA) and oxygen-ozone for the treatment of knee osteoarthritis (OA). Four randomized controlled trials (RCTs) met the following criteria: age 18 years or older; diagnosis of end-staged knee OA; intervention groups received intra-articular HA for pain management; control groups received intra-articular oxygen-ozone therapy; outcomes were pain, stiffness, and function using the visual analog scale (VAS), the Western Ontario and McMaster Universities Arthritis Index (WOMAC) questionnaire; and adverse effects. There was no significant difference between the groups regarding VAS at three months follow-up ($p=0.202$). There was significant heterogeneity of the studies ($p<0.0001$). Four studies showed no significant difference in VAS between the groups at six months ($p=0.255$). There was no significant difference in WOMAC pain scores at six months ($p=0.380$). Based on four RCTs the outcome of WOMAC for stiffness at six months was significantly improved in favor of HA ($p=0.013$), but there were no significant differences in WOMAC function ($p=0.037$) and adverse events ($p=0.837$). Limitations of the analysis include: the limited number of studies, small patient populations; heterogeneity of the studies (e.g., doses of medication, patient characteristics) and short-term follow-ups. This meta-analysis does not support ozone therapy for the treatment of knee OA.

Liu et al. (2015) conducted a Cochrane systematic review to assess the effectiveness of ozone therapy for the treatment of foot ulcers in diabetics. Three ($n=212$) randomized controlled trials “with unclear methodology” met inclusion criteria. Ozone treatment was compared to antibiotics, and usual care vs. usual care plus ozone therapy. The use of ozone did not appear to affect the number of ulcers healed or make a difference in the reduction of the ulcer area.

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 intradisally, 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 intradisical 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.

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 (Schölmerich, et al., 2017; 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). Evidence supporting the safety and clinical effectiveness of this therapy is lacking.

Huang et al. (2018) conducted a systematic review and meta-analysis of randomized controlled trials to assess the effectiveness of *Trichuris suis ova* (TSO) for the treatment of inflammatory bowel disease (IBD). Six randomized controlled trials (RCTs) that compared TSO therapy with placebo were included. Three of the included studies were registered clinical trials. Outcomes included efficacy and safety. There was no significant difference ($p>0.26$) in remission and response rates for the treatment of ulcerative colitis (3 RCTs; $n=74$). Nine patients in each group experienced one adverse event. Three studies ($n=538$) investigated TSO for the treatment of Crohn disease study. There was no significant difference in remission and response rates between the two groups. Studies were limited by the small patient populations and short-term follow-up of 12 weeks and sparse data were lacking on adverse events (gastrointestinal signs and symptoms). Meta-analysis could not draw a conclusion regarding TSO dosage due to the limited data. There was no statistically significant clinical benefit using TSO for the treatment of IBD.

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: Although proposed for a variety of conditions, over-the-counter biologics are not supported by the peer-reviewed evidence to have a positive impact on health care outcomes. 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, Q10, 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 (*Iscador*®)
- 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 weight loss (Huang, et al., 2019), allergic rhinitis, labor pain, initiation of labor, cancer-related pain, nausea and vomiting, dysmenorrhea, glaucoma, insomnia, cognitive function of older adults, uremic pruritus, and end-stage renal disease. Studies have reported conflicting outcomes or no significant improvement with acupressure compared to sham.

In a randomized controlled trial (n=162), Torkzaharni et al. (2017) reported that the use of acupressure vs. acupressure sham and control, showed no significant differences between the groups in spontaneous initiation of labor.

Makvandi et al. (2016) conducted a systematic review and meta-analysis (n=13 studies) of randomized controlled trials (RCTs) to assess the evidence regarding the effects of acupressure on duration of labor and mode of delivery. Studies were included if they examined the effect of acupressure at any acupoint during childbirth for these indications. The number of subjects in the included studies ranged from 60–212. Acupressure was applied at the SP6 acupoint in eight studies, at LI4 in three studies, at BL32, GB21, L14, BL67 and L14/SP6 in one study each. Acupressure was performed at different stages of labor across the studies (e.g., active phase of labor, second stage of labor). Acupressure increased the chance of vaginal delivery when compared with placebo/no intervention (p=0.002) and decreased the duration of the active phase by 1.310 hours (p=0.001) and the second stage of labor by 5.808 minutes (p=0.001). However, there were several limitations to the studies including: high risk of bias; inadequate and/or unclear allocation concealment; and significant heterogeneity between the studies regarding the research questions, study design, intervention protocols, and outcome measures. Additional well-conducted RCTs are needed to confirm the benefits of acupressure and to support the creation of evidence-based guidelines on the use of acupressure in this subpopulation.

Hmwe et al. (2016) conducted a systematic review of the literature to evaluate the effectiveness of acupressure in promoting sleep quality in adults. Eight randomized controlled trials met inclusion criteria. The studies were conducted in hemodialysis units, long-term care facilities, nursing homes, psychogeriatric inpatients, and in a cardiology outpatient department. Comparators were routine care or conventional medical treatment, sham, transcutaneous electrical acupoints stimulation or acupressure with light touch. The results showed that the quality of sleep was significantly improved in the acupressure group compared with usual care, but there was no difference between the acupressure and sham acupressure groups. The studies were limited by the small patient populations, heterogeneity of acupoints and methodological limitations and unclear risk of bias. Further studies with well-designed trials are needed to confirm the efficacy and safety of acupressure for sleep.

Matthews et al. (2014; reviewed 2015) 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 41 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, knee osteoarthritis, 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 (Li, et al., 2017; Bedah, et al. 2016; Cao, et al., 2012).

Ma et al. (2018) conducted a systematic review and meta-analysis of five randomized controlled trials (n=564) to assess the effectiveness of cupping for the management of ankylosing spondylitis (AS). Studies were included if cupping therapy was used as the sole intervention or as an adjunct therapy in conjunction with Western medicine therapy and patients were diagnosed with AS using definitive modified New York criteria. The primary outcome was the functional condition measured by recognized scales including the Bath Ankylosing Spondylitis Functional Index (BASFI). Other outcomes were disease activity as measured on the Bath Ankylosing Disease Activity Index (BADAI), and serum levels of erythrocyte sedimentation rate (ESR) and C reactive protein (CRP). Four studies (n=294) showed cupping plus Western medicine had a significantly better response rate than Western medicine alone ($p<0.001$). Three RCTs (n=242) showed significantly better BASFI ($p<0.001$), BASDAI ($p<0.01$), ESR ($p<0.01$), and CRP ($p<0.01$) outcomes with Western medicine plus cupping. Limitations of the analysis include the limited number of studies with small patient populations, high risk of bias, and lack of blinding to the intervention. The authors noted that caution must be taken when attempting to generalize the results of this systematic review due to the low quality of the studies and that the power of the analysis based on small sample size effects may be exaggerated. Most of included RCTs were conducted on Chinese populations making it difficult to apply the result to the general population.

Al Bedah et al. (2016) conducted a systematic review to evaluate the safety and efficacy of wet cupping. Fourteen randomized controlled trials (n=863) met inclusion criteria. The included studies evaluated wet cupping for multiple conditions including: nonspecific low back pain (three studies), hypertension (one study), brachialgia (one study), carpal tunnel syndrome (one study), chronic neck pain (two studies), metabolic syndrome (one study), migraine headaches (one study), oxygen saturation in smokers with chronic obstructive pulmonary disease (one study), physiologic and biochemical parameters of healthy individuals (two studies) and oral and genital ulcers due to Behcet disease (one study). Outcomes were conflicting with nine studies favoring cupping for various conditions and five studies reporting no statistically significant difference was seen when cupping was used. Adverse effects included fainting, discomfort, headache, skin laceration, whole body itching, pain, generalized body pain, circulatory instability, migraine attack, repeating tinnitus, and wound-healing itch. Limitations of the studies included the heterogeneity of the conditions; limited number of studies per condition; variable risk of bias; small patient populations (n=20–126) with no power of calculations; heterogeneity of treatment regimens (e.g., number of sessions, length of each session; frequency of sessions) and comparators (e.g., acetaminophen; conventional treatment, no treatment); lack of blinding; and no control for placebo effect. Due to the limitations of the studies and poor overall methodology, firm conclusions could not be made regarding the clinical effectiveness of wet cupping.

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 spondylosis". 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 spondylosis. Despite the number of RCTs included in this analysis, the authors stated that there was a lack of well-designed studies 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 may also be referred to as biomagnetic therapy, magnetotherapy, magnotherapy, static magnetic field therapy, or therapeutic magnets: The therapy involves static (unmoving)

magnets and is claimed to have healing powers. These therapeutic magnets are typically integrated into bracelets, rings, shoe inserts, magnetic mattresses and clothing. Some health care providers claim that magnets can help broken bones heal faster, but most proponents advocate that the magnets relieve pain.

Arabloo et al. (2017) conducted a technology assessment of systematic reviews of randomized and non-randomized studies that compared magnet therapy with other conventional therapies for the treatment of local pain. Eight studies met inclusion criteria. Magnet therapy was investigated for the treatment of pain in various organs, arthritis, myofascial muscle pain, lower limb muscle cramps, carpal tunnel syndrome and pelvic pain. Comparators included placebo, weak magnet, sham, chiropractic therapy, and traditional therapies. According to the results, magnet therapy was not an effective treatment for relieving different types of pain.

Magnetic Resonance Therapy (MRT): MRT, based on nuclear magnetic resonance imaging (MRI), uses low frequency, nuclear electromagnetic fields to redirect molecular activity in the body. The electromagnetic fields generated by an MRT device are around 10,000 times weaker than those used in MRI. MRT is based on the theory that the human body is controlled by electric and magnetic fields. When there is tissue damage there is interference with the normal body healing signals, inhibiting healing and tissue repair. MRT is proposed to redirect the abnormal signals into normal, healthy signals by exposing and acting on the nuclei of hydrogen atoms. This in turn is proposed to stimulate the regeneration and repair of cartilage and bone tissue. MRT is proposed for the treatment of multiple conditions including: arthritis, osteoporosis, ligament and tendon injuries, sports injuries, degenerative spine disease, autism and posttraumatic stress syndrome. Specific devices have been developed to treat different areas of the body and to treat specific conditions. Examples of these external devices include MBST® Nuclear Magnetic Resonance Therapy, MBST® OpenSystem 350, and MBST® OpenSystem 700 (MedTec Medizintechnik, Germany). Other devices include the Magnesphere™ and Halo™ Home Unit (Pico-Testa Magnetic Therapies, LLC, Clearwater, FL). MRT is a patented technology. Treatment is typically given daily in one hour sessions for 5–10 consecutive days (Kernspin MBST, 2018).

There is insufficient evidence in the published, peer-reviewed literature to support the effectiveness of MRT for any indication. Published studies have primarily been in the form of retrospective reviews, case reports and case series with small, heterogeneous patient populations (e.g., n=21-103); and short-term follow-ups (≤12 months) (Krpan, et al., 2015; Taghva, et al., 2015; Kullich, et al., 2013). Overall, randomized controlled trials have reported no significant difference in outcomes with MBST vs. placebo.

Goksen et al. (2016) conducted a randomized controlled trial (n=97) to evaluate the efficacy of therapeutic nuclear magnetic resonance (MRT) for the treatment of mild to moderate osteoarthritis (OA) of the knee. Inclusion criteria included: age 35–75 years, symptomatic OA of a single knee, and radiological stage II or III according to Kellgren and Lawrence scale. Patients received ten, one hour daily sessions of MRT on weekdays. Follow-ups occurred at two weeks and 12 weeks. Pain outcomes were measured by Visual Analogue Scale (VAS), quality of life by the SF-36 and physical function by the Western Ontario and McMaster Universities Arthritis Index (WOMAC). Ultrasound, magnetic resonance imaging and radiography were also used for knee evaluation. At weeks two and 12 following treatment, significant improvements were reported in both groups regarding pain, stiffness, physical functions and quality of life scores but there were no significant differences between the groups. There were no significant differences in ultrasonographic measurements and MRI Whole-Organ Magnetic Resonance Imaging Scores (WORMS) or acetaminophen usage between the groups. No adverse events were reported. This study showed that MRT was not superior to placebo in the treatment of OA of the knee. Author-noted limitations included failure to use objective measurements like gait analysis, walking distance, number of steps without pain and lack of evaluation of pre- and post-range knee joint motions. It was also questioned if a ten day course was the correct dosage to assess benefits and harms of MRT.

Salfinger et al. (2015) conducted a randomized controlled trial to assess the efficacy of therapeutic nuclear magnetic resonance (tNMR) for lumbar radicular syndrome (LRS) in patients (n=94) with lumbar disc herniation. Patients were randomized to the treatment group (n=48) or the control group (n=46). In addition to standard, conservative therapy, the treatment group also received seven sessions of tNMR. Patients were included who presented with lumbar disc herniation within 12 weeks of inclusion, radiation of pain into one or both legs and clinical signs of a radicular lesion. Seven treatments on consecutive days were administered. Visual Analogue Scale (VAS) scores improved significantly in both groups (p<0.000). The intensity of morning and evening pain decreased significantly in both groups (p<0.000) with a statistically significant difference in pain perception in

favor to the treatment group in week four. Before and after week four, no statistically significant differences were noted between the groups. There were no significant differences between the groups in the SF-36 physical component and mental component scores or the Roland Morris Disability Questionnaire (RMDQ) scores. There was no statistically significant difference in NSAID intake, but there was a significant decrease in the use of opiates in both groups ($p=0.05$ in study group; $p=0.024$ in placebo group). Three months following therapy, patients in the tNMR group reported a statistically significant lower duration of sick leave ($p=0.026$) compared to the control group. Both groups reported fewer absences but there was no significant difference between the groups. Fourteen patients dropped out of the study (13%). Overall, tNMR did not result in significant improvements as an adjunctive therapy for this patient population.

Kulich et al. (2006) conducted a randomized controlled trial to evaluate the effects of adjunctive MBST® ($n=30$) compared to placebo ($n=32$) for the treatment of chronic low back pain. Patients had been admitted for three-weeks of inpatient rehabilitation therapy. Treatment was given for one hour on five consecutive days. Both groups reported a significant improvement in reduction in the Visual Analogue Scale (VAS) starting at week one following treatment. The MBST group maintained the improvement in pain under stress at the three-month follow-up but the placebo group did not. Neither group maintained significant improvement in pain at rest three months after therapy. The MBST group showed a significant improvement ($p<0.001$) in the total Oswestry score at three months compared to the placebo group. The placebo groups showed a significant improvement at week one ($p<0.05$) but the improvement was not maintained. Both groups showed comparable improvement in the walking and sleeping sections of the Oswestry Questionnaire at the three-month follow-up. No adverse events were reported. Limitations of the study include the small patient population, short-term follow-up and patients were part of an inpatient rehabilitation program with multiple other therapies.

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. Studies primarily include small patient populations and short-term follow-up with lack of a sham comparator (Pan, et al., 2016). Evidence supporting the clinical effectiveness of meridian therapy for the treatment of pain and other conditions is lacking.

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. The ingredients of moxa smoke include terpene compounds, aliphatic hydrocarbons, alcohols, aromatic hydrocarbons, and their oxides. 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 heart failure (Liang, et al., 2019), polycystic ovary syndrome (Kwon, et al., 2018); spasticity following stroke (Yang, et al., 2018); chronic fatigue syndrome (Wang, et al., 2017), primary insomnia (Sun et al., 2016), osteoarthritis (Li, et al., 2016; Song, et al., 2016; 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). Firm conclusions regarding significant effectiveness of moxibustion cannot be made due to the limitation of the studies which included: small patient populations; high risk of bias; lack of reporting of adverse events (e.g., second degree burns, pruritus); heterogeneity of treatment regimens (e.g. stimulating process, original materials, duration, frequency, selection of acupoints) and control groups; and the low methodological quality of the studies. Overall moxibustion is not recommended for these indications.

Qigong Longevity: Qigong longevity exercise, or qigong (alternatively spelled chi gung or chi kung), 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. Qigong has been proposed for the prevention of disease (e.g., stroke)

and for treatment of various symptoms, conditions and diseases including fatigue, sleep, cognitive function, cancer and chemotherapy related symptoms, diabetes mellitus, hypertension, Parkinson disease, infectious diseases and chronic obstructive lung disease (Meng, et al., 2018; Lauche, et al., 2017; Van, et al., 2017; Wang et al., 2012). Due to the poor quality of the studies and high risk of bias the effectiveness of Qigong has not been established.

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. Systematic reviews have been conducted to assess the therapeutic effect of Reiki, including pain control, but firm conclusions regarding its clinical effectiveness have not been established due to the limited number of studies, small patient populations, poor study methodology, various outcome measures, and the possibility of a high level of bias (Demir, 2018; VanderVaart, et al., 2009).

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.

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.

Bio Photonic Lymphatic Drainage Treatment (BELD): BELD (Center for Natural & Integrative Medicine, Orlando FLA) is a proprietary therapeutic technological device proposed for removing blockage from the lymphatic system by repolarizing proteins throughout the body. The reversal of the polarity is proposed to remove blockages and allow elimination of toxins from the body through the urine. BELD is recommended for many conditions including: breast lumps, inflammation, chronic pain, joint pain, allergies, sinus pressure and infections, respiratory problems, headaches, prostate problems, hormone imbalance, chronic female conditions, dental trauma, heavy metal toxicity, neuromuscular, immune and fatigue syndromes. BELD is proposed to be more effective than manual massage. There is a lack of evidence in the published, peer reviewed literature to support the safety and efficacy of Bio-Photonic Lymphatic Detoxification and Drainage for any indication.

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. The process of intention,

action, gaining feedback, making decisions, and reenacting with adaptations constitutes the learning framework (Hiller and Worley, 2015).

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. Systematic reviews and meta-analysis of randomized controlled trials have investigated Pilates for the treatment of Parkinson's disease (Suarez-Iglesias et al., 2019); breast cancer; diabetes; chronic stroke; chronic obstructive pulmonary disease; cystic fibrosis; heart failure; arterial hypertension; non-specific acute, subacute or chronic low back pain. There is insufficient evidence to support the clinical effectiveness of Pilates for any condition. Studies primarily include small patient populations, short-term follow-ups and lack of significant improvement with Pilates.

A systematic review of randomized controlled trial was conducted by Miranda and Marques (2018) to investigate the effectiveness of Pilates on non-communicable diseases. Twelve studies (n=491) were included. Diagnosis included: breast cancer (three studies), diabetes (three studies), chronic stroke (two years post stroke) (two studies), chronic obstructive pulmonary disease (one study), cystic fibrosis (one study), heart failure (one study) and arterial hypertension (one study). The best-evidence synthesis revealed strong evidence for improving exercise tolerance; moderate evidence for improving symptoms, muscle strength and health-related quality of life; and limited or conflicting evidence on vital signs, metabolic parameters, body composition, respiratory function, functional status, balance, flexibility and social support. Meta-analysis was not possible due to the paucity of evidence. Limitations of the studies included: small patient populations, 4–16 weeks follow-ups, heterogeneity of study design, lack of a clear description of usual care in the control groups, and conflicting outcomes. Patient populations were mainly composed of female participants preventing generalization of results to both genders. Future studies with homogeneous outcome measures are needed to establish the effects of Pilates on these subpopulations.

In a Cochrane review of Pilates, Yamato et al. (2015) reported that no high quality evidence was found for any of the treatment comparisons, outcomes or follow-up periods investigated for the treatment of non-specific acute, subacute or chronic low back pain. There was some evidence for the effectiveness of Pilates for low back pain, but there was no conclusive evidence that Pilates was superior to other forms of exercises. Ten randomized controlled trials (n=510) met inclusion criteria.

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. There is a paucity of evidence investigating the clinical effectiveness of Tui Na

Wei et al. (2017) conducted a systematic review of the literature to assess the evidence on Tui Na for cervical radiculopathy. Five randomized controlled trials ($n=448$) investigated Tui Na alone or Tui Na combined with cervical traction. The pooled analysis from three studies indicated that Tui Na alone showed a significant immediate lowering effect on pain scores ($p=0.002$) compared to cervical traction. Meta-analysis from two trials revealed significant immediate pain lowering effects using Tui Na plus cervical traction vs cervical traction alone ($p<0.00001$). No adverse effects were reported. Limitations of the studies included: small patient populations ($n=60-120$), short treatment duration (14–28 days) and variation in treatment regimens and study methodology. Due to the weak evidence and study limitation firm conclusions could not be made. Well-designed randomized

controlled trials with large patient populations and long-term follow-ups are needed to support these findings. Also, the safety of Tui Na could not be determined from the data.

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.

Schouten et al. (2015) conducted a systematic review of the effectiveness of art therapy in trauma treatment for adults. Six controlled, comparative studies (n=223) (one randomized controlled trial) met inclusion criteria. Subjects had to be traumatized adults (independent of type of trauma or type of trauma population), and the design of the included studies had to be a comparison outcome trial with a control group. Type of trauma included posttraumatic stress disorder (PTSD), sexual assault and traumatized incarcerated women. Some of the included studies reported a significant decrease in psychological trauma symptoms in the treatment group and one study reported a significant decrease in depression. Outcomes were conflicting with studies reporting a decrease in symptom severity (some significant and some not) and no significant decrease in symptoms. The most statistically significant decrease in trauma symptom severity was found when art therapy was used with psychotherapy. Author-noted limitations of the studies included: small patient populations; methodological weakness with moderate quality at best; heterogeneity of art therapy interventions (type and duration of the interventions), control conditions, follow-up assessments, and characteristics of the study population; and patient age primarily less than 22 years. No firm conclusions can be made for the use of art therapy for this patient population.

Uttley et al. (2015) conducted a systematic review of randomized controlled trials investigating art therapy for people with non-psychotic (e.g., depression, anxiety, and phobias) mental health disorders. Eleven randomized controlled trials (n=533 patients) met inclusion criteria. Subjects included children or adolescents with asthma, sickle cell disease or post-traumatic stress disorder and adults with Alzheimer's disease, dementia, cancer, or depression and incarcerated males. Follow-ups occurred from four weeks to 12 months. Control groups included: no treatment/wait-list, attention placebo controls and psychological therapy comparators. Primary outcomes included treatment effectiveness, response as determined by changes in mental health rating scales and a variety of scales and questionnaires. There was a high risk of bias. Some studies reported significant positive effects compared to controls. Meta-analysis was not possible due to clinical heterogeneity and insufficient comparable data on outcome. Due to the small patient populations (n=18–111) and the low quality of the studies a definitive statement regarding the clinical effectiveness of art therapy could not be made for people with non-psychotic disorders.

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.

Martial Arts: Martial arts are best known as a means of self-defense and are divided into armed and unarmed sports. Many of the forms and derivatives thereof are practiced as a means of mental and spiritual development (Cochrane Complementary Medicine, 2020). Many martial arts originate in China with only 20–30% coming from other East Asian countries. Unarmed combat forms of martial arts include judo, sumo, karate and 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.

Systematic reviews of randomized and nonrandomized controlled trials have evaluated the effectiveness of Tai Chi as a supportive treatment for low back pain (Qin, et al., 2019), type 2 diabetes mellitus (n=14 studies) (Chao, et al., 2018); stroke rehabilitation (n=15 studies) (Ding, 2012) and gait training (n=5 studies) (Li, et al., 2018); 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 Tia 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.

Karkou and Meekums (2017) conducted a Cochrane systematic review to assess the effects of dance movement therapy on behavioral, social, cognitive and emotional symptoms of patients with dementia. No studies met the inclusion criteria.

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.

Systematic reviews and randomized controlled trials have reported that there is insufficient evidence to support hypnosis for insomnia (Chamine, et al., 2018; Lam et al., 2015); burn wound pain and anxiety (Provencal, et al., 2018); stress reduction (Fisch, et al., 2017); breast cancer (Cramer, et al., 2015); cancer-related anxiety, fatigue, pain (Chen, et al., 2017); management during labor and childbirth (Madden, et al., 2016), children undergoing dental treatment (Al-Harasi, et al., 2010) and treatment of irritable bowel syndrome (Webb, et al., 2007). Although some studies have reported improved outcomes with hypnosis, studies have been limited by small patient population, short-term follow-ups, and heterogeneity of treatment regimens and controls. Overall, the authors concluded that the quality of the trials was inadequate to make firm conclusions and outcomes were conflicting in some studies improvements were reported and in other studies 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. TM is one type of meditation involving a mantra meditation technique where consciousness is directed towards repetition of a word, or a phrase as an object of focus. Meditation has been proposed for the treatment of numerous conditions including: depression (González-Valero, et al., 2019), anxiety, stress (Araujo, et al., 2019), chronic pain, asthma, posttraumatic stress syndrome, hypertension, headache, dementia, attention deficit disorder and for smoking cessation. Systematic review and meta-analysis have reported some benefit from meditation but based on the poor quality of the studies firm conclusions have not been made regarding the clinical effectiveness of this modality.

Hilton et al. (2017) conducted a systematic review and meta-analysis of 38 randomized controlled trials investigating mindfulness meditation for chronic pain (e.g., back pain, headache, fibromyalgia, cancer, musculoskeletal pain, irritable bowel syndrome). Treatments ranged from 3–12 weeks. Interventions included mindfulness-based stress reduction (MBSR), mindfulness-based cognitive therapy (MBCT), and other types of meditation. Some interventions were monotherapy while others used meditation as an adjunctive therapy. Comparators included: treatment as usual, education, support groups, stress management, massage, multidisciplinary pain interventions, relaxation/stretching, nutritional information/food diaries, and cognitive-behavioral therapy. These low quality, heterogeneous studies reported some evidence that meditation was associated with a small decrease in pain. Well-designed, rigorous, and large-scale RCTs are needed to decisively provide data for the efficacy of mindfulness meditation for chronic pain.

In an analysis of eight systematic reviews (SR) and meta-analyses, Ooi et al. (2017) reported that transcendental meditation may potentially reduce systolic blood pressure by ~4 mm Hg and diastolic blood pressure by ~2 mm Hg. The SRs included 5–15 studies and follow-ups ranged from six weeks to 18 months. The outcomes were comparable to those seen with other lifestyle interventions including weight-loss and exercise. However, the

strength of evidence was considered weak due to conflicting findings across reviews and potential risks of bias. Further research is still needed to validate these findings.

Salhofer et al. (2016) conducted a Cochrane systematic review of randomized controlled trials investigating the benefits and harms of meditation as an adjunctive therapy for adults with hematological malignancies. One abstract was found. There is insufficient evidence to support meditation for this patient population.

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., 2018; 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. Zeng et al. (2018) evaluated the treatment effect of mirror therapy on motor function of the upper extremity in patients with stroke. Eleven studies (n=347) were included in the meta-analysis. Although some improvement in motor function was seen, the heterogeneity of the studies, including the patient (n=15–60) characteristics and treatment regimens, prevented firm conclusions from being drawn regarding the clinical effectiveness of mirror box therapy.

Thieme et al. (2018) investigated mirror therapy compared to no treatment, placebo/sham therapy, or other treatments for improving motor function and motor impairment after stroke. Randomized controlled trials (RCTs) and randomized cross-over trials comparing mirror therapy with any control intervention were included (n=62 studies; 1982 subjects). Mirror therapy was provided 3–7 times a week, for 15–60 minutes for 2–8 weeks (average of five times a week, 30 minutes a session for four weeks). There was moderate-quality evidence that mirror therapy had a significant positive effect on motor function and motor impairment. The authors noted that effects on motor function were influenced by the type of control intervention. Based on moderate-quality evidence, it was reported that mirror therapy may improve activities of daily living. There was low-quality evidence for a significant positive effect on pain (n=248) and no clear effect for improving visuospatial neglect (failure to orientate, to report or to respond to stimuli located on the contralesional side) (n=175). No adverse effects were reported. The major limitations of the studies included the small patient populations, short-term therapy and lack of reporting of methodological details, resulting in uncertain evidence quality.

Barbin et al. (2016) conducted a systematic review to evaluate the efficacy of mirror therapy on phantom limb pain. Five randomized controlled trials and 15 nonrandomized studies met inclusion criteria. Study methodologies were heterogeneous with low level evidence, patient populations were small and outcomes were conflicting. Meta-analysis was not possible. The data did not support the use of mirror therapy for the treatment of phantom limb pain.

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.

Systematic reviews of randomized controlled trials have investigated music therapy for individuals with multiple conditions including: dementia (11 studies; n=404) (Gómez-Romero, et al., 2017); depression (nine studies; n=421) (Aalbers, et al., 2017); substance abuse (40 studies; n=1381) (Hohman, et al., 2017); schizophrenia and schizophrenia-like disorders (18 studies; n=1215) (Geretsegger, et al., 2017); dementia (22 studies; n=1097) (van der Steen, et al., 2018); acquired brain injuries (29 studies; n=775) (Magee, et al., 2017); and symptoms of cancer (29 trials; 3731) (Bradt, et al., 2016). Although some studies suggested that music therapy may be effective for some outcomes measures, overall the quality of the studies was very low to moderate, clinical effectiveness could not be determined, outcomes were inconsistent, treatment regimens were heterogeneous, and long-term outcomes have not been reported.

In a systematic review of 51 randomized controlled trials (n=3663), Cepeda et al. (2006) 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”.

Outdoor Youth Programs: Outdoor youth programs (outdoor adventure programs, outward bound schools, outdoor education) are associated with social, recreational, developmental, educational and therapeutic aims. In general, outdoor education can be described as teaching and/or learning and/or experiencing in an outdoor and/or out-of-school environment. The content of learning and teaching varies and depends on the general aim of the program (e.g., gaining of knowledge in natural sciences; increased physical activity, leadership skills, personal and social development; survival skills; improved skills in relation to nature-oriented sports), the target group and the outdoor setting. Most programs are designed to fit the needs of a specific target group (e.g., substance abuse, school truancy, failing school) and work with teens or at-risk teens. Outdoor adventures are proposed to have direct positive impacts on well-being and perceived stress, as well as foster the psychological concepts related to resilience, self-efficacy, mindfulness and subjective well-being. Outdoor activities include backpacking, climbing, swimming, canoeing, scuba diving, and biking. Programs range from 5–30 days (Wilderness Adventures, 2019; Becker, et al., 2017; Voyageur 2017; Mutz, et al., 2016). There is insufficient evidence to support the clinical effectiveness of outdoor youth programs. Studies are primarily in the form of small case series. Currently, the key components of these programs and the benefits gained by participants have not been established.

Becker et al. (2017) conducted a systematic review of the literature (n=13 studies) to identify the potential benefits of regular compulsory school- and curriculum-based outdoor education programs (OEPs) for children and adolescents. The review concentrated on programs that were embedded within the curriculum and conducted regularly within the school schedule. These programs focused on student-centered classes and interdisciplinary subjects, hands-on learning, possibilities to explore and experience oneself and the environment, and the use of natural and cultural places as a “classroom”. Thirteen studies met inclusion criteria: nine case series, three quasi-experimental designs and one cross-sectional design. Inclusion criteria were: all types of study designs; any type of formal school- and curriculum-based outdoor education program involving children and adolescents (age 5–18 years); regular weekly or bi-weekly classes in a natural or cultural environment outside the classroom with at least four hours of compulsory educational activities per week over a period of at least two months; and at least one reported outcome on a student level. Environmental settings included gardens, local forests, prairies, farmland and sailing. Eight studies described outcomes in terms of social dimensions, seven studies in learning dimensions, and four studies included physical activity and health. Sample sizes ranged from 5–230. Eleven studies reported positive results, one study reported positive and negative results and one study reported negative effects. Tendencies indicated that regular compulsory school- and curriculum-based outdoor education programs could advance students in the physical, psychological, learning and social dimensions. However, the wide heterogeneity in the program aims, intervention length (e.g., biweekly for eight weeks vs. full weeks for six months), participant groups, age, learning environments, methodology and reported effects, prevented any firm conclusions from being made regarding the effectiveness of these programs. Evidence on the effect of these programs on physical activity and mental health were lacking.

Pet Therapy: Pet therapy (PT) or animal-assisted therapy (AAT) involves the use of animals for therapeutic purposes. PT is proposed to help people recover from and/or better cope with psychological and/or physical health problems. The intent is that pet therapy aids in the psychological, educational and physical rehabilitation of a patient to improve their general sense of well-being and improve their quality of life. Dogs and cats are the most commonly used animals. Studies have reported that pet therapy decreases cortisol and catecholamine levels in the blood and increases endorphins, reducing stress and producing a calming effect. Pet therapy has been proposed for the treatment of dementia, cognitive dysfunction, stroke, mental health disorders (e.g., depression, autism spectrum disorder), stress, pain, fatigue, cardiovascular rehabilitation, cancer support, pregnancy, post-traumatic stress disorder and hospice care. The therapy is used by inpatient facilities, nursing homes, universities, as well as at home (Zafra-Tanaka, et al., 2019; Fiori, et al., 2018; Ein, et al., 2017; O’Haire et al., 2013; Moretti, et al., 2011).

There is insufficient evidence in the peer-reviewed literature supporting the clinical effectiveness of pet therapy. Studies have primarily been in the form of case reports or case series with less than 100 subjects and studied for

a variety of conditions. Outcomes are conflicting with some studies reporting no significant difference with pet therapies (Fiori, et al., 2018; O’Haire et al., 2013; Moretti, et al., 2011).

Ein et al. (2017) conducted a systematic review and meta-analysis to examine the efficacy of pet therapy (PT) on reducing physiological stress levels (i.e., blood pressure and heart rate) and self-reported stress and anxiety scores. Studies with the following characteristics were included: subjects all ages, healthy, or had psychological and/or medical illnesses; used novel living animals (e.g., an animal that was unfamiliar to the subject and not the subject’s personal pet) as the sole therapeutic tool; used PT programs to create a calming environment with minimal physical activity (e.g., petting the animal); and incorporated pre- and post-therapy changes in blood pressure and heart rate and/or changes in self-reported measures of stress and/or anxiety. A total of 28 studies (n=1310) met inclusion criteria. All but two studies used dogs for the animal therapy. Overall, analysis of eight studies showed significantly reduced heart rates (HR) ($p<0.001$). Subgroup analysis showed that healthy subjects maintained the significant HR effect ($p=0.012$) but subjects that had medical and/or psychological conditions did not show a significant reduction in HR ($p=0.68$). Significant effects were shown in a group setting ($p=0.007$) vs. no effect in individual therapy ($p=0.403$). PT did not significantly reduce systolic blood pressure ($p=0.149$). Overall self-reported anxiety was significantly reduced in adults ($p<0.001$) and remained significant in subgroup analysis of healthy adults ($p<0.001$) and adults with a medical ($p<0.001$) or psychological condition ($p=0.001$). There were an insufficient number of subjects to determine the effect of self-reported anxiety on children and elderly adults. The authors reported that the majority of medical and psychological subjects had taken medication (e.g., pain medication) prior to or during PT. Limitations of the studies include the heterogeneous, small patient populations (n=4–135); lack of self-reported data on stress reduction; use of self-reported data; use of medication by some of the subjects before and/or during the study; and the use of only dogs in all but two of the studies.

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.

Recreational Therapy: Recreation therapy (RT), also call therapeutic recreation, is a therapy that utilizes recreation and other activity-based interventions to address the needs of individuals with illnesses and/or disabling conditions. The proposed purpose of RT is to improve or maintain physical, cognitive, social, emotional and spiritual functioning in order to facilitate full participation in life and maintain optimal levels of independence, productivity and quality of life. Recreational therapy includes: arts and crafts, sports, games, dance and movement, drama, music, and community outings. RT seeks to reduce depression, stress, and anxiety, recover basic motor functioning and reasoning abilities, build confidence, and socialize effectively. Services are provided or directly supervised by a Certified Therapeutic Recreation Specialist (CTRS). Recreational therapists practice in various settings including: inpatient and outpatient physical rehabilitation, inpatient and outpatient mental health, skilled nursing facilities and assisted living, adult day programs, park and recreation, adapted sports programs, acute care hospitals, and school systems (CTRS) (American Therapeutic Recreation Association, 2019; National Council for Therapeutic Recreation Certification, 2019). There is a lack of evidence investigating the clinical efficacy of recreational therapy.

Wilderness Therapy: Wilderness therapy (WT), also called wilderness adventure therapy (WAT), is a multi-faceted program, consisting of outdoor life and various sequenced tasks and challenges. Wilderness therapy is also used synonymously with other terms including: adventure therapy, wilderness experience programs, bush adventure therapy, eco-therapy, adventure-based counselling, outdoor adventure intervention, therapeutic camping, and outdoor behavioral healthcare. The program seeks to enhance the restorative qualities of nature combined with structured individual and group-based therapeutic work. WT offers a prevention, early intervention, and treatment modality for individuals with behavioral, psychological, psychosocial and/or substance abuse issues (Dobud and Harper, 2018; Fernee, et al., 2017; Bowen, et al., 2016). WT has, for the most part, replaced military style boot camps.

There is a wide diversity of philosophies, theories, and formats being used in WT. Activities often include rope challenge courses, group games, trust activities, residential camps, and wilderness-based expeditions. The programs are typically led by a multi-disciplinary therapist team and often serve a heterogeneous population of adolescent clients. Participants engage in group living with peers and therapists, undergo individual and group therapy sessions, and learn basic outdoor skills proposed to foster personal, emotional, and social growth. Typically, WT is a 10-week, part-time program, facilitated by three practitioners for six to eight participants. Treatment involves seven day-based adventure activities (e.g., bushwalking, cross country skiing, white water rafting), a two-day overnight training expedition, and a five-day expedition. Parents, teachers, and support workers also participate in up to eight weekly indoor adventurous problem-solving activities incorporated within group therapy sessions (Dobud and Harper, 2018; Fernee, et al., 2017; Bowen, et al., 2016).

The wilderness environment is proposed to be a healing place that may facilitate change. After having experienced difficulties, turmoil and/or loss in their lives, participants may find peace in the wilderness. A primary sense of despair may gradually be replaced by self-confidence through reflecting on life and managing the basic tasks of simple outdoor life and the inherent challenges of this approach to treatment. A proposed advantage of WT over conventional therapy is that the stigma of psychological therapy dissolves former resistance, making individual and group psychotherapy less intimidating and more natural. The duration and context of the WT treatment may provide the necessary time and space to address and process emotional upheaval, and stimulate personal issues to surface that have not been revealed in previous treatment settings (Dobud and Harper, 2018; Fernee, et al., 2017; Bowen, et al., 2016).

Alexander et al. (2016) discussed the safety concerns related to wilderness therapy and the importance of being prepared for traumatic and minor injuries and illness. Adverse events of WT may occur from contaminated water; insect and tick bites; heat-related illness; hypothermia; allergic reactions to plants; insects or foods; head injuries; fractures; sprains; dislocations; burns; lacerations; and blisters.

Studies investigating the effectiveness of wilderness therapy have primarily been in the form of case series with small heterogeneous patient populations, reporting short-term effects and investigating various outcome measures. Overall, studies on WT have not provided detailed program descriptions and guiding theories. The efficacy of WT across programs and populations and how the treatment stimulates change has not been established (Fernee, et al., 2017).

Dobud and Harper (2018) conducted a systematic review of randomized controlled trials in an effort to identify the specific activities contributing to adventure therapy (AT) outcomes. Fourteen direct comparison studies met inclusion criteria. Studies indicating the presence of qualified practitioners working in clinical settings were included. Studies without a control group or experimental conditions and lacking the presence of a therapeutic rationale or practitioner were excluded. Study groups included: adapted outward bound therapy, wilderness survival, therapeutic services with AT, integrated wilderness therapy (WT), adventure camp, and outdoor behavioral healthcare. Comparators included: traditional probation treatment; wilderness survival without family therapy; treatment as usual; no specific intervention; alternative group therapy; behavior modification, residential program, inpatient program, a second outdoor adventure program; and AT plus psychological counseling, psychological counseling alone and psychological and group counseling. In ten of the 13 studies, intense social environments were assumed to contribute to positive outcomes. Three studies reported that problem-solving activities would lead to feelings of success or mastery. Seven studies reported that time in nature and pristine wilderness environments would provide a more effective setting for therapeutic healing to occur and asserted that time in nature was an active ingredient contributing to outcomes. However, the differences were not significant. Studies were limited in number and varied regarding the treatment setting, therapeutic ingredients, social setting and outcome measures. It was noted that there was limited discussion about the experimental groups and the treatments provided made it difficult in some cases to determine whether a control group was designed to be therapeutic. Based on these studies, the authors concluded that the active ingredients regarded as unique to AT made little difference in outcomes across the 13 studies, and the unique components of AT may not have greater influence than the factors shared with all other forms of therapeutic interventions.

Fernee et al. (2017) conducted a systematic review of the literature to investigate the effectiveness of WT on adolescence (aged 12 to 18 years) and to identify the descriptions of the treatment programs and their

outcomes. Seven studies met inclusion criteria and were in the form of case series with small patient populations (n=4–47). The intent of the studies was heterogeneous and included: 1) understanding how adolescents who were involuntarily enrolled in the program responded to parents and therapists (n=13); 2) understanding how backpacking was related to self-reported outcomes for troubled adolescent women (n=9); 3) gaining insight into the effect of a residential wilderness program on self-evaluation of male adolescents and what specific aspects of the program caused the changes (n=13); 4) interviewing participants > age 20 years following involvement in a 10-day WT program at age 14–16 years to discover the impact of WT on their lives (n=4); 5) investigating WT and the outcomes from the intervention (n=4 men); 6) examining WT and identifying the key change agents and outcomes (n=12); and 7) evaluating youth well-being 24 months after the conclusion of WT treatment (n=47). Reported outcomes of the studies included: despair was gradually replaced by self-confidence; the wilderness environment was a healing place and facilitated change; time alone allowed reflection and personal insight; avoidance of the “stigma” attached to mental health treatment; physical demands of the wilderness lifestyle contributed to the changes experienced including competence and sense of accomplishment; and enhanced self-awareness, self-efficacy; and socialization skills with therapists and peers. The authors noted that the lack of client characteristics in relation to the therapeutic process and to each participant’s specific set of outcomes prevented conclusion regarding who the best candidates are for WT, as well as the programmatic circumstances that might facilitate individual change. Another limitation of the studies is the inability to generalize effects to a larger population due to the limited number of studies and small patient populations. Additional studies are needed to define a comprehensive and useful framework that is applicable to the general population and who the ideal candidates are for WT.

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, as antihypertensive lifestyle therapy, stroke rehabilitation, depression, substance abuse; posttraumatic stress disorder; treatment of cancer pain and treatment-related side effects, anxiety and stress, diabetes mellitus, schizophrenia and epilepsy, chronic non-specific low back pain; rheumatic diseases and asthma (Gothe, et al., 2019; Sieczkowska, et al., 2019; Wu, et al., 2019; Kuppili, et al., 2018; Bridges and Sharma, 2017; Broderick, et al., 2017; Lawrence, et al., 2017; Cramer, et al., 2017; Wieland, et al., 2017; Cui, et al., 2017; Yang, et al., 2016; Panebianco, et al., 2017; 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. Limitations of the studies included: small patient populations; short-term follow-ups; and heterogeneity of yoga protocols, number of sessions and length per session; and lack of blinding. Data are conflicting and studies have not been well designed. Data on adverse events is limited. Large-scale, well designed studies using objective measures and long-term follow-up are needed to draw definitive conclusions regarding the clinical effectiveness of yoga.

Multi-Therapy Systematic Reviews

Several systematic reviews have evaluated multiple CAM therapies for the treatment of various conditions including asthma, cancer, dementia, depression, diabetes, hypertension, irritable bowel syndrome, pain management (Garland, et al., 2019), 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.

Abdominal Pain: Abbott et al. (2017) conducted a Cochrane systematic review that included 18 randomized controlled trials to assess the effectiveness of four types of psychosocial therapy (cognitive behavioral therapy, hypnotherapy including guided imagery, yoga, written self-disclosure) for the treatment of recurrent abdominal pain in school-aged children. Regarding four studies on hypnotherapy (n=143), greater treatment success was reported post-intervention (p=0.0003). Reduced pain intensity (p<0.00001) and frequency (p<0.00001) were achieved with hypnotherapy compared to controls. Studies were considered low-quality with short term follow-up

and small patient populations. One study reported long-term benefit of hypnotherapy at five years (68%) compared to control (20%) ($p=0.005$). For yoga therapy compared to control, there was no evidence of effectiveness on reduction of pain intensity post-intervention ($p=0.09$). The three yoga studies included 122 children and were low-quality evidence.

Asthma: Kohn and Paudyal (2017) conducted a systematic review and meta-analysis of 23 randomized controlled trials to evaluate the safety and efficacy of CAM for the treatment of asthma in adults. CAM therapies included the following: curcumin; New Zealand green-lipped mussel; solanum xanthocarpum and solanum trilobatum; coenzyme Q10; selenium; auranofin; vitamins B6, C, D or E; aqueous extract of propolis; AKL1# (picrorrhiza kurroa, zingiber officinale, ginkgo biloba and apocynin); lactose powder; TJ-96; Pingchuan Yiqi Granule, magnesium, n-3 polyunsaturated fatty acids; and anti-asthma herbal medicine intervention (ASHMI; a Chinese herbal formula containing Ku-Shen [*Sophora flavescens*], Gan-Cao [*Glycyrrhiza uralensis*] and Ling-Zhi [*Ganoderma lucidum*]). Controls included standard asthma treatment, placebo, and pharmacotherapy. The results of meta-analysis on magnesium, vitamin C and vitamin D, indicated that these supplements were not beneficial in improving the lung function of asthma patients. Eight single trials showed improvement in lung function and symptom control but there was no overall trend in one outcome measure across trials. In addition, many of the trials had a poor methodological quality, restricting the reliability and applicability of these results. The analysis did not provide sufficient evidence to recommend any of the included CAM compounds for the treatment of asthma. Limitations of the studies included: short-term duration of treatment (range one day to 36 weeks), small patient populations ($n=14-232$), poor methodological quality; heterogeneity of treatment regimens, and the unclear or high risk of bias in the majority of studies.

Cancer: Duong et al. (2017) conducted a systematic review and meta-analysis of randomized controlled trials that compared non-physical mind and body practices with control interventions for the management of fatigue in cancer and hematopoietic stem cell transplant (HSCT) recipients. A total of 55 trials ($n=4975$) met inclusion criteria. Interventions included acupuncture or acupressure ($n=12$ studies), mindfulness meditation ($n=11$ study), relaxation techniques ($n=10$ studies), massage ($n=6$ studies), energy therapy ($n=5$ studies), energizing yogic breathing ($n=3$ studies) and others ($n=8$ studies). Mindfulness and relaxation were effective at reducing fatigue severity but the authors noted that how to translate these findings into clinical practice had yet to be determined. Acupuncture, acupressure, massage, energy therapy and yogic breathing were not effective. Limitations of the studies included: limited number of studies for some modalities; short-term treatment durations; variation in the definition of fatigue; and heterogeneity of treatment regimens, comparators (e.g., usual care, wait list, sham, education), types of cancers, and timing of interventions (before, during and/or after treatment).

In a Cochrane systematic review investigating massage therapy with or without aromatherapy for symptom relief in patients with cancer, Shin et al. (2016) reported that there was a lack of evidence on the clinical effectiveness of massage therapy for this subpopulation. Nineteen studies ($n=1274$) met inclusion criteria and were considered "very low quality evidence". Thirteen studies ($n=596$ participants) compared massage with no massage. Six studies ($n=561$) compared aromatherapy massage with no massage. Two studies ($n=117$) compared massage with aromatherapy and massage without aromatherapy. Overall, the patient populations were too small to be reliable and key outcomes (pain and psychological symptoms) were not reported. From the limited evidence available, the authors stated that they were unable to assess the effect of adding aromatherapy to massage on the relief of pain, psychological symptoms including anxiety and depression, physical symptom distress, or quality of life.

Leggett et al. (2015) conducted a systematic review of the literature to evaluate the effectiveness of oral CAM substances for women with breast cancer. Studies of women receiving or who had completed conventional treatments for breast cancer and reported using oral CAM products (e.g. tablets, capsules, powders, liquids) for the alleviation of cancer-related symptoms were included. Outcomes of the studies included treatment side effects, improvement of quality of life, physical and emotional wellbeing, survival, and mortality. Twenty-two randomized and nonrandomized controlled trials met inclusion criteria. The CAM substances included: black cohosh, a range of Chinese medicinal herbal mixtures, estrogen botanical supplements (EBS), essiac, *Ganoderma lucidum*, ginseng, glutamine, grape seed proanthocyanidin extract (GSPE), guarana, herbal remedies, and soy isoflavones. No more than four studies were found for each modality. Although there was some weak evidence for support for relief of various symptoms by various substances, the authors advised that the results should be viewed with caution due to the poor methodological quality of the studies. The overall

strength and quality rating of the body of evidence was considered to be limited. In conclusion, there was little evidence to make definitive recommendations regarding the effectiveness for individual CAM therapies in women receiving conventional treatments for breast cancer.

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.

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: Asher et al. (2017) conducted a systematic review and meta-analysis to compare the effectiveness of exercise and CAM therapies for the treatment of major depressive disorder (MDD). A total of 22 randomized controlled trials were included for direct comparisons and 127 trials were used for network meta-analyses. CAM studies included acupuncture (three studies), omega-3 fatty acids (three trials), S-adenosyl methionine (SAME) (one trial), and St. John’s wort (12 trials; n=1806). Two studies comparing aerobic exercise monotherapy with SSRIs were also included. The primary outcome measure was response to treatment on the Hamilton Depression Rating Scale (HAM-D), which was defined as a 50% improvement of scores from baseline. Overall, there was no significant difference in outcomes with the use of a CAM therapy and the risk of harms of CAM therapies was not adequately assessed. The studies were limited by the unclear randomization methods, high loss to follow up, small patient populations, inadequate dosing for the Selective serotonin reuptake inhibitors (SSRIs), and medium to high risk of bias. The overall quality of the studies was poor. The authors did caution that SSRIs may lead to more adverse events and treatment cessation when compared with acupuncture or St. John’s wort.

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 insufficient 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/cocus 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 acupuncture 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.

Fibromyalgia: Zech et al. (2017) conducted a systematic review of nine randomized controlled trials (n=457) to evaluate the efficacy, acceptability and safety of guided imagery/hypnosis (GI/H) in the treatment of fibromyalgia. Primary outcomes included: $\geq 50\%$ pain relief; $\geq 20\%$ improvement of health-related quality of life; psychological distress; disability, acceptability and safety at end of therapy; and three-month follow-up. Controls included GI/H placebo (e.g., education, emotional support, pure relaxation), usual treatment, waiting list and active pharmacological or nonpharmacological interventions. There was a significant benefit of GI/H compared to controls on $\geq 50\%$ pain relief and psychological distress at the end of therapy. Acceptability was not significantly different compared to the control. No study reported on safety. Overall, the quality of evidence was rated as low. Limitations of the studies included the small patient populations (n=16–100); short-term follow-ups (one week to six months); heterogeneity of therapies (e.g., home alone therapy, individual therapy, group therapy, non-pain related suggestions, pain-relation suggestions, number of sessions) and outcome measures. The authors noted that it was unclear if patients with anxiety and/or depressive disorder, which are frequently associated with fibromyalgia, were included in most studies. There is insufficient data to support GI/H for the treatment of fibromyalgia.

Heart Failure: Gok Metin et al. (2018) conducted a systematic review including 24 randomized controlled trials (n=1314) to evaluate the effectiveness of mind-body interventions for the treatment of high functioning individuals with heart failure. The analysis included: seven Tai Chi studies; four studies on yoga and relaxation; two studies each on meditation, acupuncture, and biofeedback; and one study each on stress management, Pilates and reflexology. Studies ranged from four minutes to 26 weeks in duration. Patient populations ranged from 8–65 per study group. Small-to-moderate improvements were reported for quality of life (14/14 studies), exercise capacity (8/9 studies), depression (5/5 studies), anxiety and fatigue (4/4 studies), blood pressure (3/5 studies), heart rate (5/6 studies), heart rate variability (7/9 studies), and B-type natriuretic peptide (3/4 studies). Due to the limited number of studies, small patient populations, short duration of the studies, and poor description of the randomization procedures conclusions could not be drawn regarding the clinical effectiveness of these interventions for the treatment of heart failure.

Inflammatory Bowel Disease: Langhorst et al. (2015) conducted a systematic review of the literature to evaluate the safety and effectiveness of CAM for the treatment of inflammatory bowel disease (IBD). A total of 36 randomized controlled trials and three controlled trials met inclusion criteria. CAM interventions included: herbal medicine (e.g., aloe-vera gel, andrographis paniculata, artemisia absinthium, barley foodstuff, boswellia serrata, cannabis, curcumin, evening primrose oil, Myrrhinil intest[®], plantago ovata, silymarin, sophora, tormentil, wheatgrass-juice, wormwood); trichuris suis ovata; mind/body interventions (e.g., lifestyle modification, hypnotherapy, relaxation training, mindfulness); and acupuncture. Studies were eligible if they assessed at least one of the following outcomes: induction or maintenance of remission, disease activity or symptom severity, quality of life, or psychological variables. Overall, the studies included small patient populations and short-term follow-ups. Due to the low number of trials for each modality and the heterogeneity of the methodology of the studies, firm conclusions could not be made. Author-noted limitations of the studies included: high risk of bias, data on compliance was not reported in almost half of the studies, lack of blinding, trials of traditional Chinese medicine were not considered; and due to the small number of trials, meta-analysis could not be performed. Because most trials tested interventions for ulcerative colitis, conclusions were mainly limited to patients with this condition.

Otitis Media: Marom et al. (2016) conducted a systematic review of CAM therapies for the treatment of otitis media in children. The CAM therapies considered included: acupuncture, homeopathy, herbal medicine/phytotherapy, osteopathy, chiropractic, xylitol, ear candling, vitamin D supplement, and systemic and topical probiotics. Overall, limitations of the studies included: small patient populations, short-term follow-ups, high dropout rates, lack of a control group, and conflicting outcomes. Following review of the data for each CAM intervention, it was concluded that CAM is not considered a treatment option of otitis media due to the limited and inconsistent evidence.

Pain Management: A systematic review of data from ten randomized controlled trials (n=1055) compared manual healing methods (i.e., massage, warm packs, other thermal manual methods, and music) to standard care, no treatment, other non-pharmacological forms of pain management in labor or placebo. Massage provided a greater reduction in pain intensity (measured using self-reported pain scales) than usual care during the first stage of labor (six trials, n=362) and second and third stage of labor (two trials). Other studies showed no clear benefit of massage over usual care for the length of labor and pharmacological pain relief. One trial reported less anxiety during the first stage of labor for women receiving massage. One trial found an increased sense of control from massage and two studies reported higher satisfaction with the childbirth experience with the use of massage. All evidence was considered low to very low in quality. Very low quality showed reduced pain and shortened labor with the use of warm packs and other thermal methods. One trial that compared manual methods with music found very low-quality evidence of reduced pain intensity during labor in the music group with no evidence of benefit for reduced use of pharmacological pain relief. Further research is needed to support the clinical benefit of these modalities during labor (Smith, et al., 2018).

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."

Pregnancy: In a 2015 Cochrane systematic review, Matthews et al. evaluated the safety and effectiveness of interventions for nausea, vomiting and retching in early pregnancy (up to 20 weeks' gestation). A total of 41 trials (n=5449) met inclusion criteria. Interventions included: acupressure, acustimulation, acupuncture, ginger, chamomile, lemon oil, mint oil, vitamin B6 and several antiemetic drugs. Acupressure and acustimulation of P6 showed no significant benefit to this subgroup. The evidence for ginger was limited and not consistent. Meta-analysis was not possible due to the heterogeneity of the patient populations, interventions, comparison groups, and outcomes measures. Selection bias risk was unclear for many studies and almost half of the studies did not fully or clearly report all pre-specified outcomes. There is a lack of high-quality evidence to support any one intervention.

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.

Rheumatic Diseases: Phang et al. (2018) conducted a systematic review of randomized controlled trials to evaluate the safety and efficacy of CAM therapies for the treatment of rheumatic diseases including rheumatoid arthritis, osteoarthritis, fibromyalgia, gout, vasculitides, systemic sclerosis, systemic lupus erythematosus,

ankylosing spondylitis and psoriatic arthritis. A total of 60 studies met inclusion criteria and included the following CAM therapies: acupuncture (n=9 studies); Ayurvedic treatment (n=3 studies); homeopathic treatment (n=3 studies); electricity (n=2 studies); natural products, nonvitamin and nonmineral (e.g., Dehydroepiandrosterone [DHEA], traditional Chinese medicine, Chuanhu) (n=31 studies); megavitamin therapies (n=8 studies); chiropractic or osteopathic manipulation (n=3 studies); and energy healing therapy (n=1 study). Most studies investigated these therapies for the treatment of rheumatoid arthritis or osteoarthritis. Minor or no adverse events were reported. Due to the poor quality of the evidence the clinical benefit of these therapies could not be established. Limitations of the studies included: small patient populations; short-term follow-ups; and heterogeneity in the study designs, treatment regimens, outcome measures, disease entities, interventions and statistical analysis.

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 Neurology (AAN): AAN (2014) conducted a systematic review of the literature to develop recommendations for CAM for the treatment of multiple sclerosis. Due to the lack of evidence or the poor quality of the evidence, AAN concluded that the evidence was insufficient to support or refute the use of Chinese medicine, hippotherapy, massage therapy, hypnosis, mindfulness training, music therapy, naturopathic medicine, neural therapy, progressive muscle relaxation, tai chi, and yoga. Bases on available studies, AAN concluded the following: 1) Ginkgo biloba is ineffective for improving cognitive function but possibly effective in reducing fatigue; 2) low-fat diet with omega-3 fatty acid supplement is probably ineffective for reducing MS-related relapse, disability, or MRI lesions, or for improving fatigue or quality of life (QOL); 3) reflexology is possibly effective for reducing MS-associated paresthesia but there is a lack of data to support or refute this modality for pain, health-related QOL, disability, spasticity, fatigue, cognition, bowel/bladder function, depression, anxiety, or insomnia.

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, updated McClafferty et al., 2017) 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 advise 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; reaffirmed 2014) 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 methodological 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 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 Medical Toxicology (ACMT) and the American Academy of Clinical Toxicology (AACT): In a 2015 Choosing Wisely statement, ACMT and AACT stated “Don’t use homeopathic medications, non-vitamin dietary supplements or herbal supplements as treatments for disease or preventive health measures”. The Societies explained that these therapies are assumed safe and effective because they are considered “natural” products. Although reliable evidence that these products are effective is often lacking, substantial evidence exists that they may cause harm. In addition, risks can occur as these substances delay or replace known effective forms of treatment or compromise the efficacy of conventional medicines. The Societies also stated that hair testing for metal poisoning screening should not be performed for screening purposes. Hair and nail testing are rarely required, frequently unreliable and provide limited utility after metal exposures.

American College of Physicians (ACP): In clinical guidelines on the nonpharmacologic versus pharmacologic treatment of adult patients with major depressive disorder (Qaseem, et al., 2016), ACP evaluated the use of complementary and alternative medicines (including acupuncture, w-3 fatty acids, S-adenosyl-L-methionine, St. John’s wort [*Hypericum perforatum*]), and did not recommend their use.

American College of Rheumatology (ACR): The ACR (2016) 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 Heart Association (AHA): AHA conducted a systematic review of the literature to review the data on the potential benefits of meditation on cardiovascular risk. Some studies suggested that meditation could have long-standing effects on the brain which provides some biological plausibility for beneficial consequences on cardiovascular risk. Studies of the effects of meditation on cardiovascular risk included stress reduction, smoking cessation, blood pressure reduction, insulin resistance and metabolic syndrome, endothelial function, inducible myocardial ischemia, and primary and secondary prevention of cardiovascular disease. Overall, the studies suggested a possible though not definitively established benefit of meditation on cardiovascular risk reduction. The overall quality and, in some cases, quantity of study data were modest. AHA stated that given the low costs and low risks of this intervention, meditation may be considered as an adjunct to guideline-directed cardiovascular risk reduction by those interested in this lifestyle modification, with the understanding that the benefits of such intervention need to be better established. Further research on meditation and cardiovascular risk in the form of randomized controlled trials, adequately powered to meet the primary study outcome, striving to achieve low drop-out rates, and including long-term follow-up are warranted (Levine, et al., 2017).

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 were 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 (2015, updated 2019) states that cancer patients using or considering complementary or alternative therapy should discuss this decision with their health care provider to ensure coordination of care. NCI notes that some complementary and alternative therapies may interfere with standard treatment or may be harmful when used with conventional treatment. Patients should 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 on Cancer-Related Fatigue™, NCCN (2019) 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 may be effective in reducing fatigue and improve sleep quality in cancer patients. NCCN (2019) listed imagery, hypnosis, distraction training, and relaxation training as nonpharmacological coping skills 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. For adult pain, NCCN (2019) lists consideration of relaxation techniques, guided imagery, hypnosis, mindfulness-based stress reduction and spiritual care for pain reduction.

Society for Integrative Oncology (SIO): In 2014, SIO conducted a systematic review of the literature to develop guidelines on integrative therapies for supportive care for breast cancer patients. The recommendations included the use of music therapy, meditation, yoga, message and/or relaxation for the relief of anxiety, stress, depression/mood and/or fatigue. In addition Qigong, mistletoe, and reflexology were recommended as supportive activities for quality of life and physical functioning. Grade A recommendations (high certainty that the net benefit is substantial) were given to meditation, relaxation and yoga for the treatment of depression/mood and Grade A for meditation for quality of life and physical functioning. The remaining recommendations were lower grades. Forty of the 53 recommendations were rated a C (moderate certainty that the net benefit is small), D (moderate/high certainty that modality has no benefit or H (moderate certainty that harms outweigh benefits). Limitations of the literature included lack of standardization of intervention and the variety of settings in which the interventions were used, (Greenlee, et al., 2014).

Veterans Administration/Department of Defense (VA/DoD): In the clinical practice guideline for major depressive disorder (MDD) (2016) the VA/DoD addressed the use of some CAM therapies. The recommendations included the following:

- There is insufficient evidence to recommend for or against yoga, tai chi, or qi gong either as monotherapy or as an adjunctive treatment to pharmacotherapy.
- For patients with mild MDD who are not pregnant or breastfeeding and who prefer herbal treatments to first-line psychotherapy or pharmacotherapy, we suggest standardized extract of St. John's wort (SJW) as a medication monotherapy (weak evidence). The guideline noted that there is not good evidence that dosing of SJW is consistent across formulations from different manufacturers.
- Suggested against using omega-3 fatty acids or vitamin D for treatment of MDD (weak evidence).

Centers for Medicare & Medicaid Services (CMS)

- National Coverage Determinations (NCD): Multiple NCDs found. Refer to the NCD table of contents link in the reference section.
- Local Coverage Determination (LCD): Multiple LCDs found. Refer to the LCD table of contents link in the reference section.

Outside the United States

According to the World Health Organization (WHO) traditional medicine (TM) is either the mainstay of health care delivery or serves as a complement to it. In some countries, traditional medicine or non-conventional medicine are termed complementary medicine (CM). Tradition and complementary medicine (T&CM) is found in almost every country in the world and has a long history of use in health maintenance and in disease prevention and treatment, especially in the treatment of chronic disease. The use of T&CM varies by country based on

culture and accessibility. T&CM products include herbs, herbal materials, herbal preparations and finished herbal products. T&CM practices include Ayurveda, traditional Chinese medicine, qigong, tai chi, yoga, thermal medicine, and other physical, mental, spiritual and mind-body therapies. Halotherapy, or salt therapy, has been used in Europe for over 20 years. In a few countries, certain types of T&CM have been completely integrated into the health care system. For example, in China traditional Chinese medicine and conventional medicine are practiced alongside each other at every level of the health-care service. By the latter half of the 19th century, homeopathy was practiced throughout Europe, Asia and North America. Homeopathy has been integrated into the national health care systems of India, Mexico, Pakistan, Sri Lanka, and the United Kingdom. The regulation of TC&M varies from country to country (WHO, 2013; WHO 2001).

European Sleep Research Society: Based on a systematic review of relevant meta-analyses, European guidelines for the diagnosis and treatment of insomnia were developed by a task force of the European Sleep Research Society. The aim of the analysis was to provide clinical recommendations for the management of adult patients with insomnia. The authors reported that there was no evidence supporting the efficacy of aromatherapy or homeopathy. Three meta-analyses on music therapy suggested a potential positive effect but the methodological quality of these studies was questionable. Root reflexology, moxibustion and meditative movement therapies, including yoga may have some potential, but likewise, the poor quality of many of the original studies made it difficult to reach clear conclusions. Due to the “very low quality” of evidence, the Society stated that complementary and alternative treatments could not be recommended for insomnia treatment (Riemann, et al., 2017).

National Institute for Clinical Excellence (NICE): In the guidance on the management of rheumatoid arthritis in adults, NICE (United Kingdom) states that adults who wish to try complementary and alternative medicine should be informed that although these therapies may provide some short-term benefit, there is little or no evidence for their long-term efficacy. Complementary therapies should not replace conventional treatment (NICE, 2018).

In a 2015 (updated 2019) guideline on the diagnosis and management of menopause, NICE stated that women should be informed that the safety and efficacy of unregulated compounded bioidentical hormones are unknown and that the quality, purity and constituents of complementary products may also be unknown. Although there is some evidence that St. John’s wort may be beneficial, there is uncertainty about appropriate dosage, persistence of effect and variation in the nature and potency of various preparations.

NICE also published a guideline (2008; updated 2017) 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 not 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.

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 (2014; reviewed 2019) stated that there is a lack of high quality evidence to support the use of omega-3 fatty acid supplements during pregnancy. However their consensus-based recommendation is that women with a low dietary intake of Omega-3 fatty acids should consider using a dietary supplement.

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.

Experimental/Investigational/Unproven

Considered Experimental/Investigational/Unproven:

CPT®* Codes	Description
90880	Hypnotherapy

HCPCS Codes	Description
A9152	Single vitamin/mineral/trace element, oral, per dose, not otherwise specified
A9153	Multiple vitamins, with or without minerals and trace elements, oral, per dose, not otherwise specified
G0176	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)
H2032	Activity therapy, per 15 minutes
J3570	Laetrile, amygdalin, vitamin B-17
M0075	Cellular therapy
S8940	Equestrian/hippotherapy, per session
S9451	Exercise classes, nonphysician provider, per session
T2036	Therapeutic camping, overnight, waiver, each session
T2037	Therapeutic camping, day waiver, each session

Considered Experimental/Investigational/Unproven when used to report chemical hair analysis:

CPT®* Codes	Description
80178	Lithium
82108	Aluminum
82175	Arsenic
82300	Cadmium
82310	Calcium; total
82525	Copper
83018	Heavy metal (eg, arsenic, barium, beryllium, bismuth, antimony, mercury); quantitative, each, not elsewhere classified
83540	Iron
83655	Lead
83735	Magnesium
83785	Manganese
83825	Mercury, quantitative
83885	Nickel
84100	Phosphorus inorganic (phosphate)
84255	Selenium
84302	Sodium; other source

HCPCS Codes	Description
P2031	Hair analysis (excluding arsenic)

Considered Experimental/Investigational/Unproven when used to report a salivary hormone panel:

CPT®* Codes	Description
80426	Gonadotropin releasing hormone stimulation panel This panel must include the following: Follicle stimulating hormone (FSH) (83001 x 4), Luteinizing hormone (LH) (83002 x 4)
82157	Androstenedione

82530	Cortisol; free
82533	Cortisol; total
82626	Dehydroepiandrosterone (DHEA)
82627	Dehydroepiandrosterone–sulfate (DHEA-S)
82670	Estradiol
82677	Estriol
82679	Estrone
82784	Gammaglobulin (immunoglobulin); IgA, IgD, IgG, IgM, each
82787	Gammaglobulin (immunoglobulin); immunoglobulin subclasses (eg, IgG1, 2, 3, or 4), each
83001	Gonadotropin; follicle stimulating hormone (FSH)
83002	Gonadotropin; luteinizing hormone (LH)
83498	Hydroxyprogesterone, 17-d
84144	Progesterone
84234	Receptor assay; progesterone
84402	Testosterone, free
84403	Testosterone, total
86001	Allergen specific IgG quantitative or semiquantitative, each allergen

HCPCS Codes	Description
S3650	Saliva test, hormone level; during menopause
S3652	Saliva test, hormone level; to assess preterm labor risk

Other Complementary and Alternative Medicine Diagnostic Testing and Therapies

Considered Experimental/Investigational/Unproven when used to report any complementary or alternative medicine diagnostic testing methods, systems, therapies or treatments listed in this Coverage Policy that do not have an assigned code:

CPT®* Codes	Description
45399	Unlisted procedure, colon
76498	Unlisted magnetic resonance procedure (eg, diagnostic, interventional)
84999	Unlisted chemistry procedure
86353	Lymphocyte transformation, mitogen (phytomitogen) or antigen induced blastogenesis
86849	Unlisted immunology procedure
90899	Unlisted psychiatric service or procedure
96379	Unlisted therapeutic, prophylactic, or diagnostic intravenous or intra-arterial injection or infusion
96549	Unlisted chemotherapy procedure
97039	Unlisted modality (specify type and time if constant attendance)
97139	Unlisted therapeutic procedure (specify)
97799	Unlisted physical medicine/rehabilitation service or procedure
99199	Unlisted special service, procedure or report

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