

**Policy #** 00898 Original Effective Date: 01/01/2025 Current Effective Date: 01/01/2025

Applies to all products administered or underwritten by Blue Cross and Blue Shield of Louisiana and its subsidiary, HMO Louisiana, Inc. (collectively referred to as the "Company"), unless otherwise provided in the applicable contract. Medical technology is constantly evolving, and we reserve the right to review and update Medical Policy periodically.

## **Services Are Considered Investigational**

Coverage is not available for investigational medical treatments, procedures, drugs, devices, or biological products.

Based on review of available data, the Company considers the use of complementary and/or alternative therapies, practices, medicine or supplements that are not supported by valid scientific evidence to be **investigational.** \*

Based on review of available data, the Company considers the use of ancillary services such as visits, imaging and other testing that are performed primarily to facilitate the delivery of an unproven/investigational service to be **investigational.** \*

Note:

Services listed in this medical policy are typically considered an exclusion under most member health insurance contracts, therefore member contract needs to be considered first.

### Note:

Prescription medications are generally subject to pharmacy benefit. Pharmacy benefits exclude coverage for over-the-counter medications, including vitamins and dietary supplements, with the exception of those required to be covered by law.

## **Policy Guidelines**

"Alternative" medicine is described as a broad range of treatments and practices that are used in place of traditional evidenced based therapies. "Complementary" medicine is a term that describes treatments and practices that are used in conjunction with traditional therapies. Other terms used to describe such practices include functional, integrative, herbalism, homeopathy, holistic, unconventional, nonconventional, nontraditional, new age and natural. Traditional medicine refers

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to the standard of practice that is widely used by the medical community and has been proven safe and efficient.

Multiple modalities of CAM are lacking data from scientific evidence-based research. Safety and efficacy of the modalities listed in Table 1 have not been determined based on the standards of Western medical practice methodologies or specific guidelines for use of the modalities have not been developed (list may not be all inclusive):

Modality	Brief Explanation of Modality
Active release technique	Relief of tissue tension using a soft tissue method (manipulation and movement) to remove fibrosis/adhesions
Acupressure	Uses fingers to apply steady force on specific pressure points to mobilize chi or life force energy to and aid in healing
Alexander Technique	Mindfulness of posture and movement to release tension and efficiently use muscles
Apitherapy	Medicinal use of honeybee products to maintain health and minimize pain.
Applied kinesiology	Belief that various muscles are linked to internal organs and glands. Evaluates structural, chemical and mental aspects of health using manual muscle testing
Aromatherapy	Uses natural plant extracts topically or through inhalation to promote health and well being
Art therapy • Color • Light • Music	Clinical use of expressive art forms to promote optimal functioning of physical and emotional health
Ayurveda	Prevention and maintenance of health through balance of thinking, diet, lifestyle and the use of herbs
Flower Therapy	Use of flower essences to promote well being and balance emotions

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Disfield the open systing	Noninvestive thereasy that stimulates healing has the
Biofield therapeutics	Noninvasive therapy that stimulates healing by the practitioner interacting with the client's field of energy and surrounding information.
Healing Touch	<ul> <li>Energy therapy where practitioners use their hands in a heart-centered way to support and facilitate physical, emotional, mental and spiritual health</li> <li>No-touch energy healing that focuses on the 11 major</li> </ul>
Pranic Healing	chakras in the body and uses the body's inborn ability to heal itself.
Reiki Qigong	• Palm/hands-on healing is used to transfer a universal energy through the palms of the hands of the practitioner to the individual to promote emotional or physical healing.
• Biofield tuning	<ul> <li>Use of tuning fork to the scan for resistance and turbulence in an individual's energy field. The body's organization energy uses the coherent vibrational frequency of the tuning fork to "tune" itself.</li> <li>Utilizes intention and vowel sounds at specific</li> </ul>
Regenetics Method	frequencies to activate a systematic "biofield cleanse" which clear out distortions within one's biofield that may be negatively impacting physical, emotional, and mental health.
Coffee Enema	Detoxes the liver by absorbing the coffee enema through the venous system in the lower part of the colon. The liver is stimulated to produce more bile and in turn flushes out toxins.
Colon Hydrotherapy	Also referred to as colon cleansing. The goal of this treatment is to remove unspecified toxins from the colon and gastrointestinal tract by eliminating accumulated feces.
Combined Electrochemical Therapy	High frequency electrical stimulation and peripheral nerve block purported to treat peripheral neuropathy by first Injection of the peripheral nerve with a local anesthetic," nutraceuticals" (mostly vitamins), followed by a high

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	frequency electrical stimulation. The techniques are purported to treat peripheral neuropathy.
Crystal healing	Proponents of this technique believe that crystals act as conduits for healing. Positive, healing energy flows into the body as negative, disease-causing energy flows out.
Cupping	Special cups are placed on the skin to create suction for the purpose of helping with pain, inflammation, blood flow, relaxation, well-being and as a type of deep tissue massage.
Dry Hydrotherapy	Treatment that uses heated water in a self-contained device such as a table or chair which circulates around the individual in a massaging or pulsing manner. (i.e., Aqua Massage)
DUTCH Testing	Dried Urine Test for Comprehensive Hormones (DUTCH) involves the collection of a small amount of urine on filtered paper one to four times a day. Mapping of hormone metabolites (cortisol, cortisone, estradiol, estrone, estriol, progesterone, testosterone, DHEA and melatonin) of the adrenal glands, sex hormones and melatonin are used to treat a multitude of aliments including sleep issues, fertility problems, stress, fatigue, decrease muscle mass or bone density, aching joints, loss of libido, lowered immunity, endometriosis, PMS, painful periods, fibrous breasts, and lowering the risk of estrogen dominant cancers such as breast, cervical, and uterine (not a comprehensive list)
Ear Candling	Ear candles are hollow cone candles made of wax-covered fabric. The pointed end is placed in the ear while the other end is lit. The warm "suction" is believed to remove earwax, improve hearing, and treat conditions like sinus infections and colds.

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Full Body Hyperthermia	Systemically targets abnormal cells and pathogens by raising the temperature of the entire body. Patients body temperature is raised to $102^{\circ}F - 104^{\circ}F$
Functional Intracellular Analysis	Evaluates and leverages an individual's interaction between nutrients and their genes, pathophysiology and biochemistry to optimize function
Gc-MAF	Gc protein (known as vitamin D(3)-binding protein) is the precursor for the principal macrophage-activating factor (MAF) and is used on the theory that it has various functions as an immune modulator. Gc-MAF is injected into the body to encourage macrophage activation, anti- angiogenic activity and anti-tumor activity.
Guided imagery	Mental images are used to stimulate or re-create the sensory perception of sights, sounds, tastes, smells, movements and images associated with touch
Hair analysis	Used to identify or monitor trace minerals or toxins in the body
High dose Vitamin C	May decrease cell proliferation in a variety of cancer cell lines (i.e., prostate, pancreatic, hepatocellular, colon, mesothelioma and neuroblastoma)
Holistic and/or Biomimetric Dentistry	Consists of alternative dental practices often using natural remedies as treatment options, using other methods to sanitize teeth and treat decay, using advanced materials and adhesives.
Homeopathy	Whole body approach where products come from plants, minerals or animals
Hydrogen peroxide therapy	Intravenously used to treat ailments such as cold, flu and sinus infections.
Hypnosis	Uses the power of suggestion to promote recovery of suppressed memories or to encourage behavior modification
Immunoimagery	Consists of guided imagery, deep relaxation exercises, visualization videos and/or audio stimulation to promote

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	healing from within using the mind-body connection to stimulate the immune system.
Intravenous Therapies <ul> <li>Antioxidant</li> </ul> Micronutrient <ul> <li>Phospholipid</li> </ul>	<ul> <li>Ingredients thought to counteract the effects of free radicals. Free radicals are substances that cause oxidative stress, which may contribute to aging ad certain diseases.</li> <li>Minerals, trace elements, amino acids, vitamins and fatty acids used to improve the physical and mental performance into old age. Also, a popular approach to treat fibromyalgia.</li> <li>Series of infusions containing phospholipids, glutathione (an intracellular antioxidant) folic acid and vitamin B12, usually given weekly.</li> </ul>
INSIGHT neuroTECH scanning	Advanced scanning technologies with reporting features. Heart Rate Variability, Surface EMG and Thermography create a neural profile for the patient.
Inversion therapy	Suspends the individual upside down to stretch the spine and relieve back pain.
Laetrile	Drug that contains purified amygdalin – a compound found in the seeds or kernels of many fruits, raw nuts, beans and other plant foods. It is converted by the body into hydrogen cyanide which is believed to be a source of anticancer effects.
Laser therapy for headache and other neurological conditions	Photobiomodulation with a low-level laser or light- emitting diode (LED) can penetrate the skin and deeper tissues, is used for numerous neurological and psychological conditions.
Leukocyte- and Platelet-rich Fibrin (L-PRF)	A blood-derived biomaterial rich in leucocytes and platelets embedded in a high-density fibrin network used in surgical applications to stimulate tissue regeneration and wound healing, especially in oral cavity.
Magnet therapy	Uses static magnets to alleviate pain and other health concerns

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Meridian therapy Myotherapy (myofunctional therapy)	Includes specialized tools, which stroke the skin in the direction of the flow of blood and lymph, improving circulation, removing toxins, lifting sagging facial contours, minimizing fine lines and wrinkles and improving radiance. Assess, treats and manages pain associated with soft tissue injury and restricted joint mobility caused by muscle or myofascia dysfunction using therapies that include muscle stretching, TENS, passive stretching, dry needling, cupping, acupressure and muscle energy techniques.
Naprapathic Medicine	(Naprapathic) manipulation, use of heat, cold, light, water, radiant energy electricity, sound, air, and/or other adjunctive therapies, focusing on the soft tissues (muscle, fascia) to treat connective tissue disorders.
Naturopathy	System that rejects the use of medication(s) and is based on the theory that diseases can be successfully treated or prevented through diet, exercise and massage.
Near Infrared Lamp Therapy	Uses light wavelengths to aid in detoxification, deep tissue healing and pain/inflammation relief. Indicated to destabilize cancer cells and aid in the process of cancer cell destruction.
Ozone therapy	Process of administering ozone gas into body to treat a disease or wound. Used to treat medical conditions by stimulating the immune system or to disinfect and treat disease.
Reflexology	Based on theory that areas of the feet, hands and ears are connected to certain body parts and systems. Applying pressure to specific areas is believed to offer a range of health benefits.
Rolfing	Technique that involves the manipulation of the fascia and soft tissue to create better alignment and balance in the body.

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Traumeel	Used for temporary relief of minor muscle and joint aches caused by strains, sprains and bruising by reducing inflammation. Traumeel is a non-standardized compounded substance which is available topically, orally and by injection.
Ultraviolet blood irradiation	Exposure of the blood to light to heighten the body's immune response and to kill infections.
Visceral manipulation therapy	Gentle manual therapy technique that assesses the relationship between the body's organs (i.e., bladder, bowel, uterus, etc.) and other structures like muscles, fascia, ligaments and joints.

The National Center for Complementary and Integrative Health <u>https://www.nccih.nih.gov/health/atoz</u> (NCCIH) lists other alternative, complementary and integrative approaches that have been used for various indications despite limited scientific evidence.

## **Background/Overview**

The practice of complementary and alternative medicine (CAM) has increasingly been implemented in many regions of the world. The application of CAM varies by culture and access to conventional modalities. Studies have indicated that individuals who choose CAM do so for various reasons including: increased demand for all health services, a desire to increase awareness of available options, dissatisfaction with existing health care services, an interest in being treated as a whole, a need for more personal autonomy and control over health care decisions, desire for a plan of care that is compatible with their values, worldview or beliefs regarding nature and the meaning of health and illness and disease prevention. These therapies are often misrepresented with the terms "natural" for safe, when the two may not be related. Many complementary and alternative therapies are based on unscientific and unproven sources. Scientific methods have not clearly established the efficacy of many of the alternative therapies and some have been proven to be ineffective or harmful. Thus, many CAM practices and procedures have not gained acceptance in the traditional medical community and are not considered to be a standard of care.

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The National Institutes of Health's Office of Alternative Medicine classified alternative therapies into the following 7 categories:

- Alternative systems of medical practice use of medicine from another culture (e.g., Ayurvedia, Chinese medicine)
- Bioelectromagnetic therapies use of electrical currents or magnetic fields to promote healing (e.g., bone repair, electroacupuncture)
- Diet and nutrition use of specific foods, vitamins, and minerals to prevent illness and to treat disease
- Herbal medicine use of plants as medicine
- Manual healing methods use of the hands to promote healing (e.g., massage, chiropractic)
- Mind-body interventions use of the mind to enhance health (e.g., hypnosis, meditation, yoga)
- Pharmacologic and biologic treatments use of various substances (e.g., drugs, serums) to treat specific medical problems.

Societies and care givers agree that understanding of the benefits of CAM therapy need to be better established. Health care workers have expressed concerns regarding mainstream healthcare education of CAM therapies as they pertain to uses and potential interactions. Concerns have been voiced that pursing CAM therapy may delay known standards of care thus potentially causing harm by postponing a well-established, lifesaving treatment.

## FDA or Other Governmental Regulatory Approval

Due to demand for CAM in the United States the number of CAM products being imported has increased. To clear up potential confusion the FDA released a draft guidance (2007) that clarifies when a CAM product is subject to the Federal Food, Drug and Cosmetic Act or the Public Health Service Act. According to the draft, any labeling of a dietary supplement that is intended to treat, prevent, cure, diagnose or mitigate a health condition will be regulated as a drug under the Federal Food, Drug and Cosmetic Act. Biological products (i.e., vaccines) will be regulated under the Public Health Service Act. The Federal Trade Commission Act of 1914 deems that homeopathic products cannot be promoted as a treatment or a cure without competent and reliable scientific evidence.

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#### **Food and Supplements**

The Dietary Supplemental Health and Education Act (DSHEA) of 1994 classifies dietary supplements as one or a more of the following: vitamins, minerals, herbals or other botanicals, amino acids, any dietary supplement used by man to supplement the diet by increasing the total dietary intake, or a concentrate, metabolite, constituent or extract, or any combination of any ingredient.

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. Per the Dietary Supplement Health and Education Act of 1994 and the Durham-Humphrey Amendment of 1951, the FDA, rather than the industry has the burden of proving that a dietary supplement is unsafe or misbranded. The FDA monitors adverse effects after dietary supplements are on the market. Manufacturers are not required to obtain premarket approval for a new dietary supplement, nor are they subject to a specified post-market surveillance period.

The FDA Center for Food Safety and Nutrition is empowered by the Federal Food and Drug Act of 1906 (The Wiley Act) to remove unsafe food substances and botanicals from the market. It also allows the FDA to monitor safe use of any substances added to food. Marketing The Federal Trade Commission (FTC) is charged with accurate marketing and advertising claims.

The FDA has warned consumers about different products labeled as homeopathic. For example, in 2017, it alerted consumers that some homeopathic teething tablets had excessive amounts of the toxic substance belladonna; in 2015, it warned consumers not to rely on over-the-counter asthma products labeled as homeopathic, because they are not evaluated by the FDA for safety and effectiveness. A 2012 systematic review of case reports and case series concluded that using certain homeopathic products (such as those containing heavy metals like mercury or iron that are not highly diluted) or replacing an effective conventional treatment with an ineffective homeopathic one can cause adverse effects, some of which may be serious.

## **Rationale/Source**

This medical policy was developed through consideration of peer-reviewed medical literature generally recognized by the relevant medical community, U.S. Food and Drug Administration approval status, nationally accepted standards of medical practice and accepted standards of medical practice in this community, Blue Cross and Blue Shield Association technology assessment program

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(TEC) and other non-affiliated technology evaluation centers, reference to federal regulations, other plan medical policies, and accredited national guidelines.

Unproven services and/or medications are, by definition, those that are not consistent with prevailing medical research that has determined the services and/or medications to not be effective for treatment of the condition and/or not to have the beneficial effect on behavioral health outcomes due to insufficient and inadequate clinical evidence from well-conducted randomized controlled trials or cohort studies in the prevailing published peer-reviewed literature. The efficacy of various alternative medicine regimens is generally unproven, and some alternative therapies have been shown to be ineffective or even harmful. The published peer-reviewed literature does not support the safety and efficacy of CAM.

The NCCIH (2015) warns of the possibility of drug interactions, direct toxicities, and contamination with active pharmaceutical agent, indicating they are among the safety concerns regarding dietary and herbal supplements. Although there is a widespread public perception that herbs and botanical products in dietary supplements are safe, research has demonstrated that these products carry the same risks as other pharmacologically active compounds. Significant drug interactions have occurred when complementary medicine has been joined with traditional medicine, negatively impacting the functional treatment and ultimate outcome. This includes biologically active forms of alternative medicine and some herbal remedies. The lack of regulation, evidence, and knowledge of these products emphasizes the need for pharmacists to accurately research their use to prevent reactions or interactions The current regulatory environment for dietary supplements in the U.S. is insufficient and presents significant public safety risks.

Numerous Cochrane Reviews focused on complementary and alternative therapies used for various indications <u>https://www.cochranelibrary.com/search</u>.

Further well-constructed studies are needed using larger sample sizes, longer durations, and comparable measures while controlling biases. Current studies lack sufficient evidence, have methodological flaws, lack replication of responses, or are of poor quality making them insufficient to support or refute the use of the CAM therapies being studied. Caution is advised in using therapies which lack sufficient evidence. However, substantial evidence exists that some therapies may be toxic or cause harm.

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## **Supplemental Information**

#### **Practice Guidelines and Position Statements**

Guidelines or position statements will be considered for inclusion in 'Supplemental Information' if they were issued by, or jointly by, a US professional society, an international society with US representation, or National Institute for Health and Care Excellence (NICE). Priority will be given to guidelines that are informed by a systematic review, include strength of evidence ratings, and include a description of management of conflict of interest.

#### American Academy of Allergy, Asthma & Immunology (AAAAI)

In their clinical review of CAM 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 therapies, the potential drug-drug and drug-herbphytochemical and vitamin interactions.

#### American Academy of Neurology (AAN)

The AAN (2014) conducted a systematic review of the literature to develop recommendations for CAM. 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.

#### American Academy of Pediatrics (AAP)

The AAP Task Force on Complementary and Alternative Medicine, the Provisional Section on Complementary, Holistic, and Integrative Medicine (2008) published guidance on the use of CAM in pediatrics. The Task Force concluded that pediatricians and other clinicians who care for children have the responsibility to advice and counsel patients about relevant, safe, effective, and age-appropriate health therapies including CAM and should routinely inquire as to whether the patient is using any specific CAM therapies. They advised the clinician to work with the parents to consider

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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. (\*)

# American College of Medical Toxicology (ACMT) and the American Academy of Clinical Toxicology

ACMT and AACT discourage use of homeopathic medications, non-vitamin dietary supplements or herbal supplements as treatments for disease or preventive health measures. They Societies explain that "natural" products are assumed safe and effective, but there is a lack of stringent quality control of the ingredients present in many herbal and dietary supplements. Reliable evidence that these products are effective is lacking and substantial evidence exists that they may cause harm. Concerns are voiced regarding delaying or replacing effective forms of treatment or compromising the efficacy of traditional medicine(s). (\*)

#### National Cancer Institute (NCI)

NCI (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. (\*) NICE (2018) put out a statement that said, "Complementary therapies should not replace conventional treatment."

#### **Medicare National Coverage**

Medicare covers acupuncture for chronic lower back pain (up to 12 treatments within a 90-day period) and may cover chiropractic care with limitations. Most types of alternative medicine are not covered by Medicare, including but not limited to massage therapy and visits to naturopathic doctors.

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## **Policy History**

Original Effective Date:01/01/2025Current Effective Date:01/01/202510/03/2024Medical Policy Committee review10/08/2024Medical Policy Implementation Committee approval. New reference policy.Next Scheduled Review Date:10/2025

\*Investigational – A medical treatment, procedure, drug, device, or biological product is Investigational if the effectiveness has not been clearly tested and it has not been incorporated into standard medical practice. Any determination we make that a medical treatment, procedure, drug, device, or biological product is Investigational will be based on a consideration of the following:

- A. Whether the medical treatment, procedure, drug, device, or biological product can be lawfully marketed without approval of the U.S. Food and Drug Administration (FDA) and whether such approval has been granted at the time the medical treatment, procedure, drug, device, or biological product is sought to be furnished; or
- B. Whether the medical treatment, procedure, drug, device, or biological product requires further studies or clinical trials to determine its maximum tolerated dose, toxicity, safety, effectiveness, or effectiveness as compared with the standard means of treatment or

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diagnosis, must improve health outcomes, according to the consensus of opinion among experts as shown by reliable evidence, including:

- 1. Consultation with the Blue Cross and Blue Shield Association technology assessment program (TEC) or other nonaffiliated technology evaluation center(s);
- 2. Credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community; or
- 3. Reference to federal regulations.

‡ Indicated trademarks are the registered trademarks of their respective owners.

**NOTICE:** If the Patient's health insurance contract contains language that differs from the BCBSLA Medical Policy definition noted above, the definition in the health insurance contract will be relied upon for specific coverage determinations.

**NOTICE:** Medical Policies are scientific based opinions, provided solely for coverage and informational purposes. Medical Policies should not be construed to suggest that the Company recommends, advocates, requires, encourages, or discourages any particular treatment, procedure, or service, or any particular course of treatment, procedure, or service.

**NOTICE:** Federal and State law, as well as contract language, including definitions and specific contract provisions/exclusions, take precedence over Medical Policy and must be considered first in determining eligibility for coverage.

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