


<b>MEDICAL POLICY</b>	<b>Complementary and Alternative Medicine (CAM) Treatments (All Lines of Business Except Medicare)</b>
<b>Effective Date: 12/01/2021</b>	Medical Policy Number: 260
  12/01/2021	Medical Policy Committee Approved Date: 10/2020; 10/2021
Medical Officer	Date

**See Policy CPT/HCPCS CODE section below for any prior authorization requirements**

**SCOPE:**

Providence Health Plan, Providence Health Assurance, Providence Plan Partners, and Ayin Health Solutions as applicable (referred to individually as “Company” and collectively as “Companies”).

**APPLIES TO:**

All lines of business

**BENEFIT APPLICATION**

Medicaid Members

*Oregon:* Services requested for Oregon Health Plan (OHP) members follow the OHP Prioritized List and Oregon Administrative Rules (OARs) as the primary resource for coverage determinations. Medical policy criteria below may be applied when there are no criteria available in the OARs and the OHP Prioritized List.

**POLICY CRITERIA**

**Notes:**

- Member benefits, which address coverage or non-coverage of specific complementary and alternative medicine treatments, may vary. Member benefit contract language takes precedent over medical policy.
- Services in this policy may exist in other Medical Policies. See [Cross References](#) for guidance.

<b>MEDICAL POLICY</b>	<b>Complementary and Alternative Medicine (CAM) Treatments (All Lines of Business Except Medicare)</b>
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Complementary and alternative medicine treatments are considered **investigational and are not covered** as a treatment of any condition. Treatments of this nature include but are not limited to the following:

- A. Autogenous lymphocytic factor
- B. Colon hydrotherapy, irrigation, cleansing and lavage
- C. Intravenous infusion including:
  - 1. Hydrogen peroxide
  - 2. Micronutrient (Myers' cocktail) for indications that are not Lyme disease
  - 3. Ozone treatment (see F.)
  - 4. Vitamin C for indications that are not Lyme disease
- D. Manual and soft tissue therapies including:
  - 1. Active release techniques®
  - 2. Craniosacral therapy (CST)
  - 3. Cupping
  - 4. Instrument assisted soft tissue mobilization (IASTM), including but not limited to the Graston Technique®
  - 5. TuiNa
- E. Mesotherapy
- F. Oxygen therapy for indications that are not Lyme disease, including ozone therapy administered directly to the tissue, intravenously, or intramuscularly
- G. Placentophagy/placenta capsules

Link to [Policy Summary](#)

### CPT/HCPCS CODES

All Lines of Business	
No Prior Authorization Required	
96360	Intravenous infusion, hydration; initial, 31 minutes to 1 hour
96361	Intravenous infusion, hydration; each additional hour (List separately in addition to code for primary procedure)
96365	Therapeutic, Prophylactic, and Diagnostic Injections and Infusions (Excludes Chemotherapy and Other Highly Complex Drug or Highly Complex Biologic Agent Administration)
96366	Therapeutic, Prophylactic, and Diagnostic Injections and Infusions (Excludes Chemotherapy and Other Highly Complex Drug or Highly Complex Biologic Agent Administration)
96367	Intravenous infusion, for therapy, prophylaxis, or diagnosis (specify substance or drug); additional sequential infusion of a new drug/substance, up to 1 hour (List separately in addition to code for primary procedure)

<b>MEDICAL POLICY</b>	<b>Complementary and Alternative Medicine (CAM) Treatments (All Lines of Business Except Medicare)</b>
-----------------------	--

96368	Therapeutic, Prophylactic, and Diagnostic Injections and Infusions (Excludes Chemotherapy and Other Highly Complex Drug or Highly Complex Biologic Agent Administration)
96369	Therapeutic, Prophylactic, and Diagnostic Injections and Infusions (Excludes Chemotherapy and Other Highly Complex Drug or Highly Complex Biologic Agent Administration)
96370	Subcutaneous infusion for therapy or prophylaxis (specify substance or drug); each additional hour (List separately in addition to code for primary procedure)
96371	Subcutaneous infusion for therapy or prophylaxis (specify substance or drug); additional pump set-up with establishment of new subcutaneous infusion site(s) (List separately in addition to code for primary procedure)
96372	Therapeutic, Prophylactic, and Diagnostic Injections and Infusions (Excludes Chemotherapy and Other Highly Complex Drug or Highly Complex Biologic Agent Administration)
96373	Therapeutic, Prophylactic, and Diagnostic Injections and Infusions (Excludes Chemotherapy and Other Highly Complex Drug or Highly Complex Biologic Agent Administration)
96374	Therapeutic, Prophylactic, and Diagnostic Injections and Infusions (Excludes Chemotherapy and Other Highly Complex Drug or Highly Complex Biologic Agent Administration)
96375	Therapeutic, prophylactic, or diagnostic injection (specify substance or drug); each additional sequential intravenous push of a new substance/drug (List separately in addition to code for primary procedure)
96376	Therapeutic, Prophylactic, and Diagnostic Injections and Infusions (Excludes Chemotherapy and Other Highly Complex Drug or Highly Complex Biologic Agent Administration)
96377	Application of on-body injector (includes cannula insertion) for timed subcutaneous injection
97124	Therapeutic procedure, 1 or more areas, each 15 minutes; massage, including effleurage, petrissage and/or tapotement (stroking, compression, percussion)
97140	Manual therapy techniques (eg, mobilization/ manipulation, manual lymphatic drainage, manual traction), 1 or more regions, each 15 minutes
98925	Osteopathic manipulative treatment (OMT); 1-2 body regions involved
98926	Osteopathic manipulative treatment (OMT); 3-4 body regions involved
98927	Osteopathic manipulative treatment (OMT); 5-6 body regions involved
98928	Osteopathic manipulative treatment (OMT); 7-8 body regions involved
98929	Osteopathic manipulative treatment (OMT); 9-10 body regions involved
Unlisted	
45399	Unlisted procedure, colon
96379	Unlisted therapeutic, prophylactic, or diagnostic intravenous or intra-arterial injection or infusion

<b>MEDICAL POLICY</b>	<b>Complementary and Alternative Medicine (CAM) Treatments (All Lines of Business Except Medicare)</b>
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97039	Unlisted modality (specify type and time if constant attendance)
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## DESCRIPTION

### Complementary and Alternative Medicine

Complementary and alternative medicine (CAM) are approaches to care that are not in the mainstream stand of care approach.<sup>1</sup> They may be practiced by those who hold medical degrees and who might also practice standard, mainstream, allopathic, or Western medicine. In addition, those who are healthcare providers with other licensure (behavioral therapist, physical therapist, psychologist, or others) may also be practitioners of CAM. Complementary treatments are those that are used along with standard medical treatments but are not themselves considered to be standard treatment. Alternative treatments are those that are used instead of standard treatments and may intend to replace mainstream approaches. Often times, treatment may not be easily categorized in one type or another. Treatments are commonly focused on a behavioral health intervention, cancer treatment, or pain management for those with chronic conditions.<sup>2</sup> A 2012 National Health Interview Survey, which was conducted by the National Center for Health Statistics, part of the Centers for Disease Control and Prevention, found that 33.2 percent of adults in the United States aged 18 years and over and 11.6 percent of children age 4 to 17 years used some form of complementary health approach in the previous 12 months.<sup>3</sup> The percentages of adults and children using complementary approaches were similar to those in previous surveys. The safety and effectiveness of CAM treatments is often not well documented or studied, i.e., an insufficient evidence-base. Reasons may include a lack of funding and time, institutions willing to perform the studies, and regulatory issues. Generating a body of evidence from which conclusions can be drawn as to whether individual treatments are safe at effective at improving overall health (and for whom) is an ongoing area of development within the National Center for Complementary and Integrative Health.<sup>4</sup>

### Treatments

Complementary and alternative medicine (CAM) treatments identified in this policy are not an exhaustive list, but rather, a list of example treatments where the evidence base is lacking:

- *Autogenous lymphocytic factor*
- *Colon hydrotherapy, irrigation, cleansing and lavage*
- *Intravenous infusion including:*
  - *Hydrogen peroxide*
  - *Micronutrient (Myers' cocktail) for indications that are not Lyme disease*
  - *Vitamin C for indications that are not Lyme disease*
- *Manual and soft tissue therapies including:*
  - *Active release technique*
  - *Craniosacral therapy*
  - *Cupping*
  - *Graston technique*

<b>MEDICAL POLICY</b>	<b>Complementary and Alternative Medicine (CAM) Treatments (All Lines of Business Except Medicare)</b>
-----------------------	--

- *TuiNa*
- *Mesotherapy*
- *Oxygen therapy for indications that are not Lyme disease including ozone therapy administered directly to the tissue, intravenously, or intramuscularly*
- *Placentophagy/placenta capsules*

**REVIEW OF EVIDENCE**

A review of the ECRI, Hayes, Cochrane, and PubMed databases was conducted regarding the use of CAM treatments in general, and specifically those identified in this policy. Since the indications for treatment within this list is quite broad, the following review is focused on high-quality systematic reviews of the evidence identified through September 2021.

Autogenous lymphocytic factor (ALF)

Autogenous lymphocytic factor (ALF) is purported to boost immunity and eliminate risk future risk of disease that could be picked up from other processes that are not from placenta or other parts of the human.<sup>5</sup> ALF is generated from an individual’s own blood. According to the United States Patent and Trademark Office, this process was patented (United States Patent: 8,449,922) in 2013.<sup>6</sup>

No systematic reviews regarding the use of ALF as a treatment for any indication were identified. A single, nonrandomized study from 1998 was identified.<sup>7</sup> Three hundred fifteen individuals were studied, including 25 controls and 290 chemically sensitive immunocompromised patients. Conclusions regarding the efficacy and safety of ALF cannot be made from the existing evidence base.

Colon hydrotherapy, colonic irrigation, colonic cleansing, and colonic lavage

Colon hydrotherapy is also known as colonics, colon cleanse, or colon irrigation and has evolved over centuries into the modern form of performing a wash of the colon or large intestine, using water to remove waste matter.<sup>8</sup> This section does include the use of colon cleansing prior to a medically indicated health screen or diagnostic study (e.g., colonoscopy).

A single systematic review was identified regarding the use of colonic cleansing for general health promotion in the lay population.<sup>9</sup> The authors conducted a narrative review of the existing evidence base, including publications from both traditional and CAM publications. Conclusions could not be drawn as the authors identified no methodologically rigorous controlled trials of colonic cleansing for general health promotion. The authors did report identifying numerous case studies and series describing adverse effects of colon cleansing.

Intravenous infusion including micronutrients (Myers’ cocktail) for indications that are not Lyme disease, vitamin C and hydrogen peroxide

<b>MEDICAL POLICY</b>	<b>Complementary and Alternative Medicine (CAM) Treatments (All Lines of Business Except Medicare)</b>
-----------------------	--

Intravenous infusion micronutrient therapy (IVMT) involves the administration of vitamins and/or minerals with the goal of treating medical problems such as fatigue, infection, or cancer, or to improve and promote overall wellness. The Myers’ cocktail is named for the late physician, John Myers, who administered a combination of magnesium chloride, calcium gluconate, thiamine, vitamin B6, vitamin B12, calcium pantothenate, vitamin B complex, vitamin C, and dilute hydrochloric acid to patients with problems such as fatigue, depression, chest pain, or heart palpitations in the 1970’s. No record documents the exact doses of each constituent.

No systematic reviews regarding the use of intravenous micronutrient therapy including the Myers’ cocktail were identified.

A systematic review of randomized controlled trials evaluating the protective role of intravenous vitamin C prior to percutaneous coronary intervention (PCI) was identified.<sup>10</sup> Meta-analyses were not performed. The Cochrane risk of bias tool for randomized trials was applied to assess bias amongst the eight included RCTs. Two trials did not report randomization strategy, though overall the authors reported risk of bias to be low. Sample sizes ranged from 21 to 532 in publications identified between 1997 and 2019. The authors reported that six types of outcomes (myocardial injury, antioxidant reservoir, ROS, inflammatory mediators, coronary perfusion index, endothelial dysfunction) showed statistically significant improvement, while three types of outcomes showed inconclusive associations (infarct size, coronary artery restenosis and cardiac contractility as assessed by LVEF). However, the overall heterogeneity of these eight trials significantly limits the ability to evaluate whether intravenous vitamin C prior to PCI has an overall health benefit. Doses varied across studies, as did timing of the intervention, and the variability of administration of other antioxidants and aspirin prior to PCI.

Intravenous hydrogen peroxide has also been investigated to treat bacterial or viral infections, migraines, chronic lung conditions, allergies and cancer.

No systematic reviews regarding the use of intravenous hydrogen peroxide as a treatment for any indication were identified. A case report was identified documenting the fatal administration of intravenous hydrogen peroxide given to an infant by mistake.<sup>11</sup>

Manual and soft tissue therapies including active release techniques, craniosacral therapy, cupping, instrument assisted soft tissue mobilization (IASTM), and TuiNa

Various methods of bodywork from ancient Eastern medicine and modern day techniques are applied with the intent of overall health promotion and healing ailments including acute and chronic pain.

Active release techniques were developed by an individual chiropractor who first published his work regarding this soft tissue method of relieving tension in the mid 1980’s under the term myofascial release.<sup>12</sup> The methodology was later patented and adopted the current terminology. No systematic reviews were identified regarding the use of active release techniques for any indication.

<b>MEDICAL POLICY</b>	<b>Complementary and Alternative Medicine (CAM) Treatments (All Lines of Business Except Medicare)</b>
-----------------------	--

Craniosacral therapy (CST) was developed in the 1970’s by a doctor of osteopathy.<sup>13</sup> Practitioners of CST apply a small amount of pressure (5 grams) with the goal of releasing restrictions in the craniosacral system, thus aiding the body in healing pain and dysfunction associated with a wide array of disorders and injury. A Cochrane systematic review was identified regarding interventions for preventing and treating low-back and pelvic pain during pregnancy.<sup>14</sup> The authors reported finding low-level evidence that craniosacral therapy may improve pregnancy-related pelvic pain, though these findings were made from one single-center, single blind study with a sample of 123 women. Another systematic review with meta-analyses included 10 randomized controlled trials with a total of 681 patients with neck and back pain, migraine, headache, fibromyalgia, epicondylitis, and pelvic girdle pain.<sup>15</sup> Amongst the trials, no serious adverse events were reported, and pooled analysis from a subset of studies suggested that CST showed a significant greater effect of a small size directly after the intervention (2 RCTs, SMD = - 0.32, 95%CI = [- 0.61, -0.02], I2 = 0%, N = 183). When compared with sham manual and non-manual therapies, at 6-months follow-up CST was found to have significant medium effect size in favor of CST (2 RCTs, SMD = - 0.59, 95%CI = [- 0.99, - 0.19], I2 = 25%, N = 138). In sensitivity analyses, the findings were reported to be robust. The authors reported that more RCT following strict design protocol are needed to corroborate the effects identified these studies. No additional systematic reviews with meta-analyses were identified.

Cupping therapy dates back to ancient Egyptian, Chinese, and Middle Eastern cultures, documented in texts as early as 1,550 B.C.<sup>16</sup> Cups used in this technique may be made of glass, bamboo, earthenware or silicone, and typically 3-7 cups are applied wet or dry for up to three minutes. Cupping may be included with other therapies as a form of deep tissue massage with the aim of helping with pain, inflammation, blood flow, and relaxation. Studies of cupping have investigated the effects on acne<sup>17</sup>, fibromyalgia<sup>18</sup>, herpes zoster<sup>19</sup>, hypertension<sup>20</sup>, pain<sup>21-23</sup>, and numerous other indications<sup>24,25</sup>. Collectively, studies of this modality are difficult to draw conclusions from regarding long term overall health benefits due to heterogeneity in the design (e.g., cupping used in conjunction with other modalities, or cupping compared to shams). While some studies find significant benefit, others report no effect or very low quality evidence from those that demonstrate benefit; beneficial effects are reported to be temporary, mild, or both. Overall, the evidence as to whether this is a beneficial treatment and for which patient populations is still lacking.

Instrument assisted soft tissue mobilization (IASTM) is a treatment applied to myofascial restrictions. By combining the application of the instruments and therapeutic exercise, the goal is to help break down collagen cross-links (scar tissue) and increase blood flow and cellular activity. The Graston Technique® is one form of IASTM, and is a patented therapy developed by an amateur athlete who collaborated with medical personnel and researchers to develop a set of stainless steel instruments to assist with soft tissue lesions and fascial restrictions.<sup>26</sup> Three systematic reviews were identified; the use of IASTM is not supported by the current evidence base.<sup>27-29</sup>

TuiNa massage manipulation, pronounced twee-nah massage originated in ancient China and is believed to be the oldest system of bodywork. It’s one of the four main branches of traditional Chinese medicine. It’s based on the theory that imbalances of qi or vital life force or energy, can cause blockages or imbalances that lead to pain and illness. Practitioners use oscillating and pressure techniques such as acupressure, myofascial release and reflexology that differ in force and speed to massage muscles and

<b>MEDICAL POLICY</b>	<b>Complementary and Alternative Medicine (CAM) Treatments (All Lines of Business Except Medicare)</b>
-----------------------	--

tendons and uses manipulation to realign the body. Passive joint movements are used to restore function to muscles and joints. To enhance the effects, herbal poultices or compresses, lotions, and salves are used. A large body of systematic reviews of studies (many, RCT's) conducted in China and Korea were identified, evaluating the effects of tuina massage in pediatric and adult indications including, but limited to anorexia nervosa, chronic fatigue syndrome, hypertension, irritable bowel syndrome, and musculoskeletal disorders.<sup>23,30-44</sup> A Cochrane systematic review was also identified, evaluating manual methods of pain management in labor, which included tuina.<sup>45</sup> Collectively, these studies report the following:

- High or unclear risk of bias
- No symptom improvement
- No benefit over comparison group
- Results from methodology that is not reproducible
- In those reporting an improvement, authors state that it appears to be from very-low-quality evidence
- Need for additional high-quality studies

#### Mesotherapy

Mesotherapy involves the subcutaneous injection of small quantities of substances, such as vitamins, silica, or lecithin, for the purpose of fat or wrinkle reduction.<sup>46</sup> No systematic reviews were identified regarding the use of mesotherapy for non-cosmetic (medical) indications.

#### Ozone therapy for indications that are not Lyme disease

Ozone is a form of oxygen and may be referred to in the literature as “medical ozone”. Practitioners have reported the application of ozone therapy in gas and liquid form to treat numerous medical conditions and as a topical disinfectant. In the past decade, there have been over a dozen systematic reviews published regarding the use of ozone therapy as a treatment for a wide range of indications.

In 2019 the United States Food and Drug Administration issued a federal document in the Code of Federal Regulations regarding the dangers of ozone administration, including the following text:<sup>47</sup>  
*(a) Ozone is a toxic gas with no known useful medical application in specific, adjunctive, or preventive therapy. In order for ozone to be effective as a germicide, it must be present in a concentration far greater than that which can be safely tolerated by man and animals.*

*(b) Although undesirable physiological effects on the central nervous system, heart, and vision have been reported, the predominant physiological effect of ozone is primary irritation of the mucous membranes. Inhalation of ozone can cause sufficient irritation to the lungs to result in pulmonary edema. The onset of pulmonary edema is usually delayed for some hours after exposure; thus, symptomatic response is not a reliable warning of exposure to toxic concentrations of ozone. Since olfactory fatigue develops readily, the odor of ozone is not a reliable index of atmospheric ozone concentration.*



<b>MEDICAL POLICY</b>	<b>Complementary and Alternative Medicine (CAM) Treatments (All Lines of Business Except Medicare)</b>
-----------------------	--

Placentophagy/placenta capsules

The act of postpartum women consuming their placenta (placentophagy) encapsulated, cooked and raw has been practiced in North American since the 1970’s as an act to prevent postpartum depression and other perceived health benefits.<sup>48</sup>

A Centers for Disease Control and Prevention (CDC) Morbidity and Mortality Weekly Report regarding a case of late-onset group B *Streptococcus agalactiae* (GBS) bacteremia in an infant in Oregon was published in 2017.<sup>49</sup> The infant’s illness was found to be attributable to high maternal colonization secondary to consumption of GBS-infected placental tissue. The mother ingested placenta capsules that were processed by a commercial company for consumption. According to the report, the commercial company states on their website that placenta is cleaned, sliced and dehydrated, then ground and placed into gelatin capsules and stored at room temperature. However, there are no standards that exist for processing placenta for human consumption. The CDC report recommended that clinicians should inquire about a history of placenta ingestion in cases of late-onset GBS infection, and educate mothers interested in placenta encapsulation about the potential risks.

No systematic reviews were identified regarding placenta consumption for any indication.

**CLINICAL PRACTICE GUIDELINES**

No US-based clinical practice guidelines based on research were identified that recommend any of the treatments listed in this policy for any indication.

National Comprehensive Cancer Network (NCCN)

No clinical practice guidelines from the National Comprehensive Cancer Network were identified recommending any of the therapies in this policy.

Society of Obstetricians and Gynaecologists of Canada (SOGC)

In 2019, the SOGC published a statement summarizing the reported benefits and harms of consumption of human placenta, including recent concerns from the U.S. Centers for Disease Control and Prevention about placental encapsulation.<sup>50</sup> SOGC stated that “there is no documented evidence of benefit for improved iron stores, mood, or lactation in any of the studies that meet critical review and standards of evidence. In addition to potential harm, there is now documented harm related to placental consumption. As such, in the absence of strong evidence showing benefits and absence of harm, the SOGC does not recommend the practice of placentophagy.”

**POLICY SUMMARY**

<b>MEDICAL POLICY</b>	<b>Complementary and Alternative Medicine (CAM) Treatments (All Lines of Business Except Medicare)</b>
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Complementary and alternative medicine (CAM) are approaches to care that are not in the mainstream standard of care approach. The safety and effectiveness of individual CAM treatments are frequently not well supported by a sufficient evidence base. Research into these practices is an ongoing area of development. Some studies report benefits, though the size of the effect and time period associated with the effects are still unclear. No clinical practice guidelines based on research were identified specifically recommending CAM treatment for any indication. More research is needed with sufficient design to draw conclusions about overall benefits and safety for many CAM treatments.

## **INSTRUCTIONS FOR USE**

Company Medical Policies serve as guidance for the administration of plan benefits. Medical policies do not constitute medical advice nor a guarantee of coverage. Company Medical Policies are reviewed annually and are based upon published, peer-reviewed scientific evidence and evidence-based clinical practice guidelines that are available as of the last policy update. The Companies reserve the right to determine the application of Medical Policies and make revisions to Medical Policies at any time. Providers will be given at least 60-days notice of policy changes that are restrictive in nature.

The scope and availability of all plan benefits are determined in accordance with the applicable coverage agreement. Any conflict or variance between the terms of the coverage agreement and Company Medical Policy will be resolved in favor of the coverage agreement.

## **REGULATORY STATUS**

### Mental Health Parity Statement

Coverage decisions are made on the basis of individualized determinations of medical necessity and the experimental or investigational character of the treatment in the individual case. In cases where medical necessity is not established by policy for specific treatment modalities, evidence not previously considered regarding the efficacy of the modality that is presented shall be given consideration to determine if the policy represents current standards of care.

## **MEDICAL POLICY CROSS REFERENCES**

- Biofeedback and Neurofeedback
- Chelation Therapy for Non Overload Conditions
- Chiropractic Care (All Lines of Business Except Medicare)
- Hyperbaric Oxygen Therapy (All Lines of Business Except Medicare)
- Hyperbaric Oxygen Therapy (Medicare Only)
- Lyme Disease
- Outpatient Physical Therapy (All Lines of Business Except Medicare)
- Subcutaneous Hormone Pellet Implant

<b>MEDICAL POLICY</b>	<b>Complementary and Alternative Medicine (CAM) Treatments (All Lines of Business Except Medicare)</b>
-----------------------	--

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<b>MEDICAL POLICY</b>	<b>Complementary and Alternative Medicine (CAM) Treatments (All Lines of Business Except Medicare)</b>
-----------------------	--

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MEDICAL POLICY	Complementary and Alternative Medicine (CAM) Treatments (All Lines of Business Except Medicare)
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