

1 **Clinical Practice Guideline:**           **Homeopathy**  
 2  
 3 **Date of Implementation:**           **February 9, 2006**  
 4  
 5 **Product:**                               **Specialty**  
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7  
 8 **GUIDELINES**

9 American Specialty Health – Specialty (ASH) considers homeopathy as unproven because  
 10 it lacks credible scientific evidence to show its clinical efficacy is similar to or better than  
 11 standard means of treatment or diagnosis. Homeopathy should not be used as a substitute  
 12 for a treatment of known effectiveness in cases where its use would place the patient at  
 13 risk.  
 14

15 **DESCRIPTION/BACKGROUND**

16 Homeopathy is a system of treatment that uses infinitesimal amounts of animal, vegetable,  
 17 and mineral preparations to treat health conditions. Homeopathic substances are extremely  
 18 dilute preparations of the original substance.  
 19

20 Developed by the 18<sup>th</sup> century physician and chemist Samuel Hahnemann, homeopathy is  
 21 built on two basic premises. First, the ‘law of similars’ or ‘like cures like’ principle states  
 22 that a remedy that causes a certain symptom (e.g., a headache) in healthy volunteers can  
 23 be used to treat a headache in individuals who suffer from it. The second principle is the  
 24 ‘law of infinitesimals.’ This principle provides that the substance being used must be  
 25 subjected to successive dilutions and that the remedies become stronger rather than weaker  
 26 when submitted to these dilutions. After each dilution the compound is subjected to  
 27 ‘potentization’ (i.e., vigorous shaking of the mixture).  
 28

29 Homeopathy defines the potency of its remedies according to how diluted they are; the  
 30 more diluted, the stronger the remedy. The potency is defined in terms of a number and a  
 31 letter indicating the dilution factor and number of dilutions.  
 32

33 The principle of infinitesimals is contrary to current conventional scientific principles and  
 34 therefore lacks credibility in that discipline. The principle of infinitesimals is counter to the  
 35 well-established principle of dose-response which holds that the more of an active  
 36 ingredient is present, the more effect it will have. This relationship of dose to response has  
 37 been demonstrated in clinical trials and through the biochemical actions of conventional  
 38 therapeutic agents.  
 39

40 Also contributing to low credibility is that many of the dilutions that are used in  
 41 homeopathy (e.g., those greater than 12c) contain no molecules of the original substance.  
 42 Further, the theory of infinitesimals raises the issue of why the minute impurities that are

1 inevitably present in any solution do not themselves become ‘potentized’ and therefore  
2 clinically active during the successive dilutions and shakings.

3  
4 When Samuel Hahnemann, the creator of homeopathy, developed this homeopathic  
5 dilution system in the late 18<sup>th</sup> century Avogadro’s number ( $6.023 \times 10^{23}$ ) was unknown,  
6 Per Avogadro’s number, homeopathic preparations more dilute than 12c would no longer  
7 contain any of the original substance and are purely placebos (Mahata, 2017). Homeopathy  
8 theorizes, based on quantum electrodynamics, that there are structures called coherent  
9 domains in water that carry information after serial dilutions and are influenced by other  
10 molecules, electromagnetic fields, etc. Electron microscopy, diffraction, and DNA array  
11 results are consistent with the presence of nanoparticles in homeopathic remedies.  
12 Homeopathic theories purport that disturbances of the human organism affect the spin on  
13 electrons of different elements within the body. Using homeopathic preparations of an  
14 agent similar to the electromagnetic force that created the problem may serve to reset the  
15 disturbance and thus restore the good health of the organism.

16  
17 The mechanism of how homeopathic healing effects are produced is unknown, but there  
18 are theories involving multiple mechanisms including such possibilities as epigenetic  
19 influences on gene expression, and alterations of the microbiome.

20  
21 In the United States, homeopathic remedies are subject to regulation by the Food and Drug  
22 Administration (FDA). Although regulated, the FDA treats homeopathic remedies  
23 significantly differently from other products. Homeopathic remedies are not required to be  
24 approved by the FDA prior to sale, not required to prove either safety or effectiveness prior  
25 to being sold, not required to label their products with expiration dates, and not required to  
26 undergo finished product testing to verify contents and strength. Homeopathic drugs have  
27 their own imprints that, unlike conventional drugs, do not have to identify their active  
28 ingredients on the grounds that they have little or no active ingredients. In many other  
29 countries (e.g., the United Kingdom), homeopathic medicines are sold over the counter.

### 30 **EVIDENCE REVIEW**

31  
32 There are numerous randomized controlled trials (RCTs) on homeopathy. There are also  
33 several meta-analyses and systematic reviews of these trials. Below is a summary of these  
34 reviews.

35  
36 A meta-analysis by Linde et al. (1998) reviewed 89 different RCTs that met the inclusion  
37 criteria. The investigators calculated the odds-ratio that the clinical effects of homeopathy  
38 were greater than that of placebo. The analysis found the resultant odds ratio was 2.45:1 in  
39 favor of there being effects greater than that of placebo. There are several reasons to be  
40 cautious about these findings. The authors themselves concluded the following: “The  
41 results of our meta-analysis are not compatible with the hypothesis that the clinical effects  
42 of homoeopathy are completely due to placebo. However, we found insufficient evidence

1 from these studies that homeopathy is clearly efficacious for any single clinical condition”  
 2 (Linde et al., 1998). In other words, although overall there appeared to be affects greater  
 3 than placebo, this cannot be said of any specific treatment and disease state. This in fact is  
 4 the greatest technical criticism of this meta-analysis: it is not a valid use of meta-analytic  
 5 technique to aggregate studies of different conditions and different interventions. Finally,  
 6 the authors of the study also make this concluding remark relative to the theoretical  
 7 foundations of homeopathy, “Even if positive findings from similar trial sets were found  
 8 in the future, pharmacologists and other scientists are likely to remain doubtful unless  
 9 plausible mechanisms are discovered.”

10  
 11 Three separate systematic reviews have evaluated the overall quality of homeopathic trials  
 12 and found them to be generally of low quality. Most importantly, one analysis found that  
 13 most of the positive results attributed to homeopathy are to be found in the studies of lowest  
 14 quality (Linde et al., 2001; Jonas et al., 2001; Cucherat et al., 2000).

15  
 16 Weiner and Ernst (2004) carried out a critical review of the literature on acupuncture and  
 17 related modalities, herbal therapies, homeopathy, and spinal manipulation. Included in the  
 18 review were 798 cases within 2 systematic reviews of homeopathy. Some evidence exists  
 19 to support the superiority of homeopathic remedies over placebo for treating osteoarthritis  
 20 and rheumatoid arthritis. The authors concluded that while the use of complementary and  
 21 alternative modalities for the treatment of persistent musculoskeletal pain continues to  
 22 increase, rigorous clinical trials examining their efficacy are needed before definitive  
 23 recommendations regarding the application of these modalities can be made.

24  
 25 An analysis done for the National Health Service in Great Britain was even more cautious  
 26 (Center for Reviews and Dissemination, 2002). It also noted the relative low quality of  
 27 studies and made this observation, “All conclusions about effectiveness should be  
 28 considered together with the methodological inadequacies of the primary studies and some  
 29 of the systematic reviews.” Its ultimate conclusion relative to inclusion of homeopathic  
 30 services in the health care system was, “There are currently insufficient data either to  
 31 recommend homeopathy as a treatment for any specific condition, or to warrant significant  
 32 changes in the provision of homeopathy.”

33  
 34 Ernst (2010) evaluated the evidence for and against the effectiveness of homeopathy. All  
 35 Cochrane reviews were discussed narratively due to the heterogeneity that existed in the  
 36 studies, precluding meta-analysis. The findings did not show that these medicines have  
 37 effects beyond placebo. One other Cochrane review was published since then and found  
 38 similar results. In 2013, Hahn did a meta-analysis of pooled clinical data on homeopathy.  
 39 His conclusion was that many of the clinical trials demonstrated a statistically significant  
 40 effect of homeopathy. This prompted academicians to perform alternative analysis to  
 41 demonstrate lack of effect leading to flawed results as diseases were inappropriately pooled  
 42 for analysis. The author suggests that further meta-analysis should focus on a specific

1 disease or group of diseases and the use of homeopathy to reduce error in statistical  
2 interpretation. To this effect, Boehm et al. (2014) studied homeopathy in the treatment of  
3 fibromyalgia. The results of the studies as well as the case reports define a sufficient basis  
4 for discussing the possible benefits of homeopathy for patients suffering from fibromyalgia  
5 syndrome although any conclusions based on the results of this review have to be regarded  
6 as preliminary. Mathie et al. (2014) completed a review on RCTs that used individualized  
7 homeopathic treatments. Thirty-two eligible RCTs studied 24 different medical conditions  
8 in total. They concluded that medicines prescribed in individualized homeopathy may have  
9 small, specific treatment effects. Findings are consistent with sub-group data available in  
10 a previous 'global' systematic review. Caution when interpreting the results should be taken  
11 given the low or unclear overall quality of the evidence.

12  
13 Stub et al. (2016) studied the adverse effects of homeopathy via a systematic review and  
14 meta-analysis of RCTs. A total of 28 trials (68%) reported adverse effects and 5 trials  
15 (12%) reported homeopathic aggravations. The meta-analysis (including 6 subgroup  
16 comparisons) demonstrated that no significant difference was found between homeopathy  
17 and control with OR 0.99, 95% CI 0.86-1.14, I (2) =54%. Authors concluded that adverse  
18 effects including the concept of homeopathic aggravations are commonly reported in trials.  
19 The meta-analysis demonstrated that the proportion of patients experiencing adverse  
20 effects to be similar for patients randomized to homeopathic treatment compared to patients  
21 randomized to placebo and conventional medicine. Perry et al. (2017) completed an  
22 overview of systematic reviews of complementary and alternative therapies for  
23 fibromyalgia. The individual studies had to be randomized controlled trials where the  
24 intervention was compared to placebo, treatment as usual or waitlist controls to be  
25 included. The primary outcome measure was pain, and the secondary outcome measure  
26 was adverse events. There was low-quality evidence that acupuncture improves pain  
27 compared to no treatment or standard treatment, but good evidence that it is no better than  
28 sham acupuncture. The evidence for homeopathy, spinal manipulation and herbal  
29 medicine was limited. Mathie et al. (2017) completed a rigorous systematic review and  
30 meta-analysis focused on RCTs of non-individualized homeopathic treatment. Authors  
31 tested the null hypothesis that the main outcome of treatment using a non-individualized  
32 (standardized) homeopathic medicine is indistinguishable from that of placebo. An  
33 additional aim was to quantify any condition-specific effects of non-individualized  
34 homeopathic treatment. Authors concluded that the quality of the body of evidence is low.  
35 Reliable evidence is lacking in condition-specific meta-analyses, precluding relevant  
36 conclusions. Better designed and more rigorous RCTs are needed in order to develop an  
37 evidence base that can decisively provide reliable effect estimates of non-individualized  
38 homeopathic treatment.

39  
40 A commentary on the continued discussion around the research approach used in meta-  
41 analysis of homeopathic research was authored by Vithoulkas in 2017. The article  
42 discussed the immanent problems of meta-analyses selecting a number of independent

1 trials in homeopathy, within which, the purpose was to examine the effectiveness of  
2 homeopathic treatment. The author sought to clarify that the complex effects of  
3 homeopathic treatment known from history and day-to-day practice have not been  
4 respected so far. The examination of most of the homeopathic trials showed that studies  
5 rarely account for homeopathic principles, in order to assess the effectiveness of the  
6 treatment. The main flaw was that trials reflect the point of view that the treatment with a  
7 specific remedy could be administered in a particular disease. However, homeopathy aims  
8 to treat the whole person, rather than the diseases and each case has to be treated  
9 individually with an individualized remedy. Furthermore, the commonly known events  
10 during the course of homeopathic treatment, such as ‘initial aggravation’ and ‘symptom-  
11 shift’ were not considered in almost all the studies. Thus, only few trials were eligible for  
12 meta-analyses, if at all. The author concludes that a better understanding of homeopathic  
13 principles would provide guidelines for homeopathic research, which are more acceptable  
14 to both homeopathy and conventional medicine.

15  
16 Cukaci et al. (2020) analyzed and summarized the evidence and plausibility of  
17 homeopathic treatment effectiveness. Authors compiled results systematically to support  
18 their conclusion that there is no evidence that homeopathic remedies have any therapeutic  
19 effect, which goes beyond that of a placebo.

20  
21 A systemic review and meta-analysis were completed by Stub et al. (2020) evaluating the  
22 adverse effects of homeopathic treatments. Forty-one studies were included, and a separate  
23 eighteen studies were specifically reviewed for comparison of adverse events during the  
24 use of homeopathy vs. control (conventional medications and herbal preparations). Eighty  
25 seven percent of the studies reported adverse events. The incidence of adverse effects was  
26 significantly higher for the control groups using conventional medicines and herbs than for  
27 the homeopathy group. Homeopathic aggravation, a transient worsening of symptoms  
28 when starting homeopathic remedies, is not generally considered a side effect, and was less  
29 often documented. The authors noted, “development and implementation of a standardized  
30 reporting system of adverse effects in homeopathic studies is warranted in order to facilitate  
31 future risk assessments.”

32  
33 Kass et al. (2020) studied the effectiveness and cost-effectiveness of the addition of  
34 homeopathy to care contracts in Germany. Information from 2,524 participants was  
35 included. There was significantly better clinical effectiveness and cost-effectiveness in the  
36 homeopathy participants who suffered from migraine, asthma, atopic dermatitis, and  
37 depression. Authors urged caution in interpretation due to study design and other  
38 limitations.

39  
40 Scaciota et al.(2021) completed a Cochrane evaluation of nine systematic reviews of  
41 treatment for irritable bowel syndrome. Four randomized controlled trials with 307  
42 participants included treatment with homeopathy. Homeopathic treatment showed a small

1 improvement in symptoms of irritable bowel compared to placebo, but evidence level was  
2 low to very low. When individual data was analyzed from the RCTs there was no difference  
3 between homeopathy and conventional treatments. Certainty of evidence was classified as  
4 very low because of methodological limitations, small sample size and short follow-up  
5 periods. One meta-analysis of 197 participants showed very low-quality evidence for  
6 homeopathy when compared to placebo. There was no report of abdominal pain or stool  
7 character in these studies. No adverse events reported.

8  
9 A meta-analysis of homeopathic *Arnica montana* for reducing post-operative pain,  
10 bleeding, motion limitation, and swelling was performed by Gaertner et al. (2021). Twenty-  
11 two studies and 28 comparisons including those comparing arnica to placebo, active control  
12 or no treatment were reviewed. The overall effect size was small and not quite at the level  
13 of statistical significance. The authors noted that the heterogeneity of the studies likely  
14 caused the lack of significance of the results. The heterogeneity included the types of  
15 surgical procedures, measures of pain management, type of control used, dosage, whether  
16 homeopathic rationales were used, and if the arnica was used as a preventative or  
17 therapeutic agent. The author stated, “If only those studies that used placebo-controls and  
18 VAS measures of pain are considered descriptively, then the effect of Arnica can be  
19 quantified as lying between a reduction of 5 and 9 mm visual analogue scale (VAS) pain  
20 rating.” Per the authors, when evaluating only the studies comparing arnica with  
21 prescription NSAIDs or paracetamol, overall effects of arnica and medications are largely  
22 comparable. However, many studies were not randomized.

23  
24 Wagenknecht et al. (2022) performed a systematic review of eighteen studies with 2,016  
25 patients to evaluate the effectiveness of homeopathy on the toxicity of cancer treatments,  
26 time to drain after mastectomy, survival, quality of life, global health, and subjective well-  
27 being in patients with cancer. Results were heterogeneous with some studies demonstrating  
28 significant differences in quality of life or toxic effects of treatments and some showing no  
29 difference or worsening with homeopathic remedies. The studies were mostly of low  
30 methodological quality.

31  
32 Gartlehner et al. (2022) used a cross-sectional study and meta-analysis to study reporting  
33 bias in trials of homeopathy. Nearly 38% of registered trials of homeopathy were not  
34 published and 50% of published RCTs were not registered. One quarter of the primary  
35 outcomes were altered after the trial was registered. There were substantially larger  
36 treatment effects reported in unregistered trials. These findings were said by the authors to  
37 likely affect the validity of the homeopathic evidence.

38  
39 Gaertner, et. al. (2023) set out to establish standardized recommendations for analyzing  
40 evidence from homeopathic intervention studies (HomIS). The authors reported five  
41 recommendations for systematic reviews and meta-analyses: “1) A broad literature search  
42 including special archives and consideration of so-called grey-literature; 2) The inclusion

1 of controlled observational studies alongside randomized controlled trials; 3) The choice  
 2 of a clear clinical research question in the terms that, if possible, the review project includes  
 3 studies with predominantly homogeneous populations, interventions, comparators and  
 4 outcomes (PICO); 4) The use of a global quality assessment including the assessment of  
 5 external, model and internal validity; 5) A summary of evidence using the GRADE-  
 6 approach if the body of evidence is sufficiently large and homogenous or a descriptive  
 7 summary if it is not so.”

8  
 9 Schulz, et. al. (2023) reviewed common criticisms of homeopathy in literature from 1950  
 10 to 2020 and evaluated the Introduction, Methods, Results and Discussion (IMRaD)  
 11 characteristics of the publications. Fifteen articles that had a focus on criticizing  
 12 homeopathy met inclusion criteria. There were five basic groupings of criticism  
 13 proclaiming that homeopathy: 1. Contradicts current laws of physics, chemistry, and  
 14 modern medicine; 2. Lacks a scientific basis; 3. Is based on faith and ideology such as a  
 15 religion or sect; 4. Is dangerous, deceptive, wastes resources, and is ethically unjustifiable;  
 16 and 5. Lacks clinical empirical evidence. Only four out of the fifteen articles met the  
 17 majority of IMRaD criteria scoring a seven on an 11-point scale.

18  
 19 Six meta-analyses of homeopathic studies met inclusion criteria for evaluation by Hamre,  
 20 et. al. (2023). Studies were from 1943 to 2014, included individualized and non-  
 21 individualized treatments, and averaged sample sizes of 45-97 patients in between 16 to  
 22 110 studies. Significant positive effects were noted for homeopathy compared with  
 23 placebo. The individualized homeopathy showed the highest positive outcomes.

24  
 25 In a randomized, controlled trial, Kaur, et. al. (2023) evaluated 129 patients with moderate  
 26 and severe Covid-19 who received either only standard of care per the study hospital’s  
 27 protocols or standard of care and homeopathic treatment. Standard care included  
 28 remdesivir, corticosteroids, antibiotics, Ivermectin, multivitamins and anticoagulants. The  
 29 homeopathic treatments were chosen after a detailed evaluation of patient symptoms and  
 30 personal history. Homeopathic remedies were administered orally except for patients who  
 31 were intubated and received the treatment through a feeding tube. The treatment groups  
 32 who received homeopathic care had fewer days requiring oxygen therapy (primary  
 33 outcome), shorter hospitalizations, faster conversion of positive to negative polymerase  
 34 chain reaction testing, lower mean score on the Clinical Outcome Ordinal Scale, and more  
 35 rapid normalization of laboratory markers.

### 36 37 **PRACTITIONER SCOPE AND TRAINING**

38 Practitioners should practice only in the areas in which they are competent based on their  
 39 education, training, and experience. Levels of education, experience, and proficiency may  
 40 vary among individual practitioners. It is ethically and legally incumbent on a practitioner  
 41 to determine where they have the knowledge and skills necessary to perform such services  
 42 and whether the services are within their scope of practice.

1 It is best practice for the practitioner to appropriately render services to a member only if  
 2 they are trained, equally skilled, and adequately competent to deliver a service compared  
 3 to others trained to perform the same procedure. If the service would be most competently  
 4 delivered by another health care practitioner who has more skill and training, it would be  
 5 best practice to refer the member to the more expert practitioner.

6  
 7 Best practice can be defined as a clinical, scientific, or professional technique, method, or  
 8 process that is typically evidence-based and consensus driven and is recognized by a  
 9 majority of professionals in a particular field as more effective at delivering a particular  
 10 outcome than any other practice (Joint Commission International Accreditation Standards  
 11 for Hospitals, 2020).

12  
 13 Depending on the practitioner’s scope of practice, training, and experience, a member’s  
 14 condition and/or symptoms during examination or the course of treatment may indicate the  
 15 need for referral to another practitioner or even emergency care. In such cases it is prudent  
 16 for the practitioner to refer the member for appropriate co-management (e.g., to their  
 17 primary care physician) or if immediate emergency care is warranted, to contact 911 as  
 18 appropriate. See the *Managing Medical Emergencies (CPG 159 – S)* clinical practice  
 19 guideline for information.

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