

1 **Clinical Practice Guideline:** **Acupuncture Point Injection Therapy (APIT)**

2
3 **Date of Implementation:** **July 16, 2009**

4
5 **Product:** **Specialty**

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7
8 **GUIDELINES**

9 American Specialty Health – Specialty (ASH) clinical committees have determined that
10 acupuncture point injection therapy (APIT) is not medically necessary for any indications.
11 Based on the available literature, it has been determined that APIT is no more effective
12 than acupuncture. Acupuncture, for the purposes of this policy, refers to solid needles
13 without injection. Additionally, the safety profile of APIT has not been established.

14
15 **DESCRIPTION/BACKGROUND**

16 Acupuncture point injection therapy (APIT) is a procedure in which pharmaceuticals,
17 vitamins, herbal extracts, or other liquid agents are injected—using a syringe and needle—
18 into intramuscular, intradermal, or subcutaneous tissue at a site corresponding to the
19 location of an acupuncture point. It emerged in China during the 1950’s as an
20 amalgamation of traditional Chinese medicine (TCM) and modern biomedicine. According
21 to Sha et al (2016), adherents hypothesize that the injected fluid enhances the effect of
22 acupuncture by creating an additional synergistic effect thought to have longer and more
23 sustainable effects than needling alone. There are several agents that are commonly used
24 for injections. These include saline, pharmaceutical agents (e.g., botulinum, cortisone, and
25 lidocaine), biological agents (e.g., herbal extracts and vitamins) and homeopathic
26 remedies. The purpose of this policy is to provide a scientific overview and assessment of
27 the current evidence base for the safety and effectiveness of APIT.

28
29 Within the United States of America, the professional requirements for performing APIT
30 and the agents approved for injection vary widely by state.

31
32 **EVIDENCE REVIEW**

33 Most of the evidence from randomized controlled trials (RCTs) is equivocal because of
34 underpowered RCTs and subjective outcomes.

35
36 One study conducted by Xu in 2005 for premenstrual syndrome demonstrated injections of
37 Huangqi (astragalus root) at acupuncture points ST 36 & SP 6 along with acupuncture was
38 more effective than drug therapy. Another study conducted by Zhou et al.(2007) for
39 trigeminal neuralgia found injections of vitamin B12 at acupuncture point ST 7 more
40 effective than drug therapy (Tegretol). Wade et al. (2016) completed an RCT of
41 acupuncture point injection treatment for primary dysmenorrhea. The investigators
42 attempted to determine if injection of vitamin K3 in an acupuncture point is optimal for the

1 treatment of primary dysmenorrhea, when compared to 2 other injection treatments (saline
2 acupuncture point injection and vitamin K3 deep muscle injection). Patients in each group
3 received 3 injections at a single treatment visit. Patients in all 3 groups experienced pain
4 relief from the injection treatments. The authors concluded that acupuncture point injection
5 of vitamin K3 relieved menstrual pain rapidly and may be a useful treatment.

6
7 Hou et al. (2015) studied acupoint injection of onabotulinumtoxin A (BoNTA) for
8 migraines. The purpose of this study was to evaluate and compare the effectiveness of fixed
9 (muscle)-site and acupoint-site injections of BoNTA for migraine therapy in a randomized,
10 double-blinded, placebo-controlled clinical trial extending over four months. Subjects with
11 both episodic and chronic migraines respectively received a placebo ($n = 19$) or BoNTA
12 (2.5 U each site, 25 U per subject) injection at fixed-sites ($n = 41$) including
13 occipitofrontalis, corrugator supercilii, temporalis and trapezius, or at acupoint-sites ($n =$
14 42) including Yintang (EX-HN3), Taiyang (EX-HN5), Baihui (GV20), Shuaigu (GB8),
15 Fengchi (GB20) and Tianzhu (BL10). BoNTA injections at fixed-sites and acupoint-sites
16 significantly reduced the migraine attack frequency, intensity, duration, and associated
17 symptoms for four months compared with placebo ($p < 0.01$). The efficacy of BoNTA for
18 migraines in the acupoint-site group (93% improvement) was more significant than that in
19 the fixed-site group (85% improvement) ($p < 0.01$). BoNTA administration for migraines
20 is effective, and at acupoint-sites shows more efficacy than at fixed-sites. Further blinded
21 studies are necessary to establish the efficacy of a low dose toxin (25 U) introduced with
22 this methodology in chronic and episodic migraines.

23
24 The four systematic reviews evaluated varied greatly in their rigor and methodology. Two
25 showed minimal evidence in support of injection therapy (Bernstein, 2001; Lee et al.,
26 2005). One showed no evidence of further therapeutic effect from regular needling
27 (Cummings and White, 2001) and one demonstrated neither strong evidence for nor against
28 injection therapy (Staal et al., 2008). In 2009, Staal et al. concluded that the effectiveness
29 of injection therapy for low back pain is still debatable and there is insufficient evidence to
30 support its use for low back pain. They suggest however, that there may be a sub-group of
31 patients who may benefit from it.

32
33 Bernstein (2001) proclaimed support for APIT, though the study was flawed. While it did
34 assess the included studies per evidence-based medical guidelines, there were at least 15
35 disparate surgical and injection interventions included without any aggregation of the data.
36 Only two interventions were relevant with minimal evidence: (1) local glycosaminoglycan
37 injection for lateral epicondylitis and (2) nonspecific injections for painful shoulder showed
38 limited (level 3) evidence supporting efficacy.

39
40 Lee et al. (2005) did not follow standards of systematic reviews by including 10 studies
41 (out of 15) based on animal research with minimal assessment of the remaining clinical
42 trials. Only two studies, one each for rheumatoid arthritis and osteoarthritis, were RCTs

1 and those were underpowered, with one only using self-reported subjective measures as
2 outcomes.

3
4 Wang et al (2015) performed a systematic review of the effectiveness of APIT with
5 Vitamin B12 for patients with incomplete recovery from Bell’s Palsy. The investigators
6 found that APIT with B12 was superior to acupuncture alone. The results suggested that
7 29% of Bell’s Palsy patients who received APIT with B12 were more likely to achieve
8 complete recovery than those with acupuncture alone. The main outcome measure was a
9 favorable improvement of at least two (2) points in the House-Brackmann scale. (or an
10 equivalent score using an alternate scoring system). Among the five (5) studies evaluated
11 in the review, the sample sizes were small ranging between 30 and 38. The authors reported
12 that due to the methodological issues and insufficient sample sizes for the studies included,
13 their results were unreliable and further research is called for with more rigorous study
14 designs.

15
16 Du and Liu (2021) evaluated the effects of injecting acupuncture points with mecobalamin
17 on the motor function of 60 participants who had suffered from cerebrovascular accidents.
18 The control group was treated with conventional stroke therapies. Injections were
19 administered once a day for fourteen days. Acupoint therapy was found to improve
20 neurological deficits and motor function in the lower extremities, activities of daily living
21 and quality of life more than conventional treatment.

22
23 Zhai, et. al. (2022) randomly divided forty participants with diabetic neuropathy into two
24 groups of twenty each. One group received intramuscular mecobalamin injections into
25 muscles surrounding the hip and the second group was given acupuncture injections of
26 mecobalamin at Zusanli (stomach 36) acupuncture points bilaterally. Outcomes were
27 measured by the Toronto Clinical Neuropathy Score and diffusion tensor imaging (MRI-
28 DTI) at baseline and 2 weeks after treatments. The neuropathy scores in both groups
29 decreased and the difference in reduction between the two groups was not significant. The
30 MRI-DTI parameters showed that acupuncture injection with mecobalamin had greater
31 therapeutic effects on the neuropathy than the intramuscular injections.

32
33 A number of more recent systematic reviews and one meta-analysis demonstrate better
34 adherence to methodological quality, yet they all similarly conclude that although
35 individual studies may seem promising, a reliable conclusion about the effectiveness of
36 APIT may not be drawn at this time. Further research of better quality must occur first.
37 (Wang et al., 2015; Cho et al., 2018; Huang et al., 2019; Xie et al, 2020; Yang et al., 2020).

38
39 Xue et. al. (2023) studied 90 patients undergoing laparoscopic sleeve gastrectomy with
40 general anesthesia. Two thirds of the patients were randomized to receive anisodamine
41 injections into the ST 36 acupuncture point and the other third became the control group.
42 Post-operative nausea and vomiting at days 1-3 and 3 months was monitored. Other

1 outcomes such as recovery from anesthesia, gastrointestinal function, sleep quality,
2 anxiety, depression, and other complications were measured. Forty two percent of patients
3 in the treatment group experienced vomiting compared with 72.4% of the control group.
4 The treatment group required less antiemetic medication and had a longer delay in needing
5 the first dose as compared to the control group. Neither the incidence of nausea nor the
6 other recovery indicators were different between the treatment and control group.

7 8 **SAFETY**

9 Acupuncture point injection therapy (APIT) has greater safety concerns than acupuncture.
10 These concerns include inappropriate injection agent selection, allergic or other adverse
11 reactions to the injected substance, and improper injection site and/or technique. The
12 literature includes harmful effects from injection therapy such as an outbreak of
13 methicillin-resistant *Staphylococcus aureus* (MRSA) (Murray et al., 2008), sciatic nerve
14 injury causing drop foot (Sobel et al., 1997), and respiratory depression and hemiplegia
15 due to pneumocephalus (Nelson and Hoffman, 1998). In 2015, an outbreak of thirty-three
16 cases of extrapulmonary tuberculosis infection in China was traced to APIT (Jia et al.,
17 2015).

18
19 In their qualitative review, Sha et al (2016) noted an increase in reports of adverse effects
20 during their review period between 2010 and 2015. The safety of APIT has not been
21 established; however, APIT inherently poses more risk for adverse events than
22 acupuncture. APIT, while considerably riskier than acupuncture, seems to be relatively safe
23 with the application of appropriate aseptic procedure to avoid infection and needle insertion
24 safety guidelines to avoid organ puncture.

25 26 **PRACTITIONER SCOPE AND TRAINING**

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

32
33 It is best practice for the practitioner to appropriately render services to a patient only if
34 they are trained to competency, equally skilled, and adequately competent to deliver a
35 service compared to others trained to perform the same procedure. If the service would be
36 most competently delivered by another health care practitioner who has more skill and
37 training, it would be best practice to refer the patient to the more expert practitioner.

38
39 Best practice can be defined as a clinical, scientific, or professional technique, method, or
40 process that is typically evidence-based and consensus driven and is recognized by a
41 majority of professionals in a particular field as more effective at delivering a particular

1 outcome than any other practice (Joint Commission International Accreditation Standards
2 for Hospitals, 2020).

3
4 Depending on the practitioner’s scope of practice, training, and experience, a patient’s
5 condition and/or symptoms during examination or the course of treatment may indicate the
6 need for referral to another practitioner or even emergency care. In such cases it is essential
7 for the practitioner to refer the patient for appropriate co-management (e.g., to their primary
8 care physician) or if immediate emergency care is warranted, to contact 911 as appropriate.
9 See the *Managing Medical Emergencies (CPG 159 – S) clinical practice guideline for*
10 *information.*

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