

1 **Clinical Practice Guideline:** **Techniques and Procedures Not Widely**
 2 **Supported as Evidence-Based**

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 4 **Date of Implementation:** **July 21, 2010**

5
 6 **Product:** **Specialty**
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 9 **GUIDELINES**

10 American Specialty Health – Specialty (ASH) clinical committees have established that a
 11 technique and/or procedure that is unproven, poses a significant health and safety risk
 12 and/or is scientifically implausible requires specific informed consent from members. Such
 13 consent must include a signed written attestation that the patient understands the current
 14 state of the evidence for, and the possible risks associated with, a technique or procedure
 15 prior to receiving it. Information from associated Clinical Practice Guidelines (CPGs) may
 16 be included as appropriate. The list of techniques and/or procedures in this guideline is not
 17 exhaustive; included are those techniques and procedures that have been specifically
 18 evaluated by ASH clinical committees and determined to pose a significant health and
 19 safety risk, to be scientifically implausible, or to be unproven based on the current state of
 20 the literature.
 21

22 Prior to receiving it, patients must be informed verbally and in writing if any procedure or
 23 treatment technique is considered experimental/investigational or unproven, poses a
 24 significant health and safety risk, and/or is scientifically implausible. If the patient decides
 25 to receive this procedure or treatment, they must sign a *Member Billing Acknowledgment*
 26 *Form* (for Medicare use *Advance Beneficiary Notice of Non-Coverage form*) indicating
 27 they understand they are assuming financial responsibility for any service-related fees.
 28 Further, the patient must sign an attestation indicating that they understand what is known
 29 and unknown about, and the possible risks associated with such techniques prior to
 30 receiving these services. All procedures, including those considered here, must be
 31 documented in the patients’ medical record. Finally, prior to using
 32 experimental/investigational or unproven procedures, those that pose a significant health
 33 and safety risk, and/or those considered scientifically implausible, it is incumbent on the
 34 practitioner to confirm that their professional liability insurance covers the use of these
 35 techniques or procedures in the event of an adverse outcome.
 36

37 **PROCESS AND DEFINITIONS**

38 The ASH clinical procedure assessment process evaluates diagnostic and therapeutic
 39 procedures against professionally recognized standards of practice, current scientific
 40 evidence, and consensus of appropriate experts. The recommendations of the consensus
 41 panel are considered by ASH clinical committees when developing criteria, definitions,

1 and processes to support clinical decision-making within ASH’s clinical management
2 system.

3
4 When developing, reviewing, and approving clinical policy, ASH peer-review committees
5 consider whether the technique/procedure:

- 6 • Is evidence-based with support from clinically relevant scientific information
7 which:
 - 8 ○ Can be used to inform the diagnosis or treatment of a patient.
 - 9 ○ Meets industry standard research quality criteria.
 - 10 ○ Is adopted as credible by an ASH clinical peer review committee.
 - 11 ○ Has been published in an acceptable peer-reviewed clinical science resource.
- 12 • Is established as clinically effective/established as having diagnostic utility by:
 - 13 ○ Scientific information published in an acceptable peer-reviewed clinical science
14 resource.
 - 15 ○ The consensus opinion of the Evidence Evaluation Committee (EEC) when
16 available.
- 17 • Is professionally recognized by:
 - 18 ○ Inclusion in the educational standards accepted by the majority of the
19 professions’ educational institutions.
 - 20 ○ Wide acceptance and use of the practice.
 - 21 ○ Recommendations for use made by healthcare practitioners practicing in the
22 relevant clinical area.
- 23 • Poses a health and safety risk.
- 24 • Is plausible or implausible.
 - 25 ○ A belief, theory, or mechanism of health and disease that can be explained
26 within the existing framework of scientific methods, reasoning and available
27 knowledge is considered plausible.
 - 28 ○ A treatment intervention or diagnostic procedure that requires the existence of
29 forces, mechanisms, or biological processes that are not known to exist within
30 the current framework of scientific methods, reasoning and available
31 knowledge is considered implausible.
- 32 • Is approved by the appropriate federal regulatory agency and being used for the
33 purpose defined in that approval (unless it is considered an off-label use or
34 otherwise meets the generally accepted standards of medical practice).
 - 35 ○ This criterion applies to drugs, biological products, devices, and any other
36 product or procedure that must have final approval to market from the U.S.
37 Food and Drug Administration (FDA) or any other federal government body
38 with authority to regulate the technology. However, approval by the FDA or
39 other federal regulatory agency does not imply that the technology is
40 automatically considered by ASH as medically necessary or the accepted
41 standard of care.

Other Considerations

Substitution harm (indirect harm): Compromised clinical outcomes caused by:

- Utilizing a specific diagnostic or therapeutic procedure when the safety, clinical effectiveness, or diagnostic utility is either unknown or is known to be unsafe, ineffective, or of no diagnostic utility, *instead of* a diagnostic or therapeutic procedure known to be safe, be clinically effective, or to have diagnostic utility.
- The utilization of a diagnostic or therapeutic procedure that is substantially less effective or safe than another procedure with established safety, and clinical effectiveness or utility.

Labeling effects (non-specific harm): The harm that results from identifying in a patient a condition or a finding that is not clinically valid.

| Technique / Procedure* |
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| ABO Blood Typing for Diagnosis and/or Treatment |
| Actra-Rx |
| Acutonics/Sonotonics |
| Addictionology |
| Advanced Biostructural Correction (ABC) |
| Antineoplastons |
| Antioxidant Function Testing (e.g., Spectrox™) |
| Apitherapy |
| Applied Kinesiology (AK) |
| Aromatherapy |
| Ashiatsu Oriental Bar Therapy (See the <i>Ashiatsu Oriental Bar Therapy (CPG 82 –S)</i> policy) |
| Aura Healing |
| Auto-Urine Therapy (or Urine Therapy) |
| Autogenous Lymphocytic Factor |
| Ayurvedic Medicine (Herbal Therapies) |
| Bach Flower Remedies |
| Bee Sting Therapy |
| Bio Energetic Synchronization Technique (BEST) |
| Bio-Cranial Therapy (BCT) |
| Bioenergetic Sensitivity and Enzyme Therapy (BioSET) |
| Biofield CanCell (Entelev) Therapy |
| Bio-Geometric Integration (BGI) |
| Biological Terrain Assessment (BTA) |
| BioMagnetic Therapy |
| Bio-oxidative Therapy (e.g., ozone, hydrogen peroxide, singlet oxygen) |
| Bovine Cartilage Products |

| Technique / Procedure* |
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| Carbon Dioxide Therapy |
| Cari-Loder Regimen (lofepramine plus phenylalanine with B12) |
| Cellular Therapy |
| Chelation Therapy for Atherosclerosis (See the <i>IV Chelation Therapy (CPG 104 –S)</i> policy) |
| Clinical Kinesiology |
| Coley's Toxin |
| Colonic Irrigation |
| Colorpuncture |
| Concept Therapy |
| Contact Reflex Analysis (CRA) |
| COVID-19 (any non-FDA-approved therapy aimed at prevention or treatment of COVID-19 or associated illnesses.) |
| CranioSacral Therapy (See the <i>CranioSacral Therapy (CST) (CPG 35 –S)</i> policy) |
| Cupping (See the <i>Instrument-Assisted Soft Tissue Mobilization (CPG 89-S)</i> policy) |
| Directional Non-Force Technique (DNFT) |
| Dry Hydrotherapy/Aquamassage/Hydromassage |
| Dry Needling (not acupuncture) (See the <i>Dry Needling (CPG 178 – S)</i> policy) |
| Ear Candling |
| Electro-Meridian Diagnosis Category: <ul style="list-style-type: none"> • BioMeridian (Meridian Stress Assessment [MSA] Machine) • ElectroAcupuncture by Voll (EAV) • Electrodermal Screening Test (EDST) • Ryodoraku/Electro Meridian Imaging (EMI) • Vega testing |
| Essiac |
| Extracorporeal Shock Wave Therapy (ESWT) for Musculoskeletal Conditions |
| Fasting |
| Force Recording and Analysis System (FRAS) |
| Fresh Cell Therapy |
| Functional Intracellular Analysis, also known as: <ul style="list-style-type: none"> • Essential Metabolic Analysis; • Intracellular Micronutrient Analysis; • Leukocyte Nutrient Analysis; and/or Micronutrient Analysis |
| Gemstone and/or Crystal Therapy |
| Hair Mineral Analysis (See the <i>Hair Mineral Analysis – Nutritional Management (CPG 103 - S)</i> policy) |
| Holistic Kinesiology |
| Immuno-Augmentive Therapy (IAT) |

| Technique / Procedure* |
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| Infrasonic/Infrasonic Therapy |
| Insulin Potentiation Therapy |
| Intensive Model of Therapy (See the <i>Intensive Model of Therapy (CPG 286 –S)</i> policy) |
| Intracellular Nutrient Analysis |
| Intravenous: Micronutrient Therapy (Myers’ Cocktail) |
| Intravenous Nutrient Therapy |
| Inversion Therapy (See the <i>Inversion Therapy (CPG 107 – S)</i> policy) |
| Iridology |
| Iscador (Mistletoe) |
| Jaffe-Mellor Technique (JMT) |
| Kelley/Gonzalez Therapy |
| Laetrile |
| Laser Therapy (See the <i>Laser Therapy (CPG 30 – S)</i> policy) |
| Live Blood Cell Analysis |
| Manual Muscle Testing – to evaluate Internal/Visceral disorders |
| Manual Muscle Testing – to evaluate Psychological disorders |
| Markerless 3D kinematic and kinetic motion analysis and report, Comprehensive full body computer-based |
| Matrix Repatterning / Energetics |
| MEDEK Therapy (See the <i>MEDEK Therapy (CPG 276 –S)</i> policy) |
| Medicinal Mushrooms |
| Megavitamin Therapy (Orthomolecular Medicine) |
| Mesotherapy |
| Micronutrient Panel Testing |
| Mistletoe (Iscador) |
| MTH-68/H Vaccine |
| Moxibustion – Direct (See the <i>Moxibustion CPG 48 – S)</i> policy) |
| Nambudripad’s Allergy Elimination Technique (NAET®) |
| Needle Implants (Intradermal Needles, Ear tacks, etc.) (See the <i>Intradermal Needles and Ear Tacks (CPG 50 –S)</i> policy) |
| Network Spinal Analysis (NSA) |
| Neural Therapy |
| Neuro Emotional Technique (NET) |
| Neuro Organizational Technique (NOT) |
| Neuro Vascular Dynamics (NVD) |
| Neurogenx |
| Neuro-Linguistic Programming (NLP) |
| Neurolink |
| New-Stim Bio-Kinetics |

CPG 133 Revision 19 – S

Techniques and Procedures Not Widely Supported as Evidence-Based

Revised – June 20, 2024

To CQT for review 05/13/2024

CQT reviewed 05/13/2024

To QIC for review and approval 06/04/2024

QIC reviewed and approved 06/04/2024

To QOC for review and approval 06/20/2024

QOC reviewed and approved 06/20/2024

| Technique / Procedure* |
|---|
| Non-invasive Interactive Neurostimulation (e.g., InterX®- all types) (See the <i>Non-invasive Interactive Neurostimulation (InterX®)</i> (CPG 277- S) policy) |
| Organ/Visceral Manipulation |
| Organic Acid Testing |
| Ortho-Bionomy |
| Peat Therapies <ul style="list-style-type: none"> Balneotherapy |
| Phage Therapy |
| Polarity Therapy (Energetic Healing) |
| (Poon's) Chinese Blood Cleaning |
| Prolonged Fasting Programs |
| Purging |
| Prolotherapy (See the <i>Prolotherapy</i> (CPG 94 – S) policy) |
| Radionics |
| Reflexology |
| Regenerative Medicine (Stem Cell Treatments, Platelet-rich Plasma Injections) |
| Regenokine Therapy |
| Reiki |
| Rife Therapy/Rife Machine |
| Sacro-Occipital Technique (SOT) TM (See the <i>Sacro Occipital Technique (SOT)</i> (CPG 96 - S) policy) |
| Sarapin Injections (See the <i>Acupuncture Point Injection Therapy (APIT)</i> (CPG 118 – S) policy) |
| Shark Cartilage Products |
| SonoKinesthesia Treatment |
| Surrogate Testing |
| Therapeutic Touch Therapy (See the <i>Therapeutic Touch Therapy</i> (CPG 106 – S) policy) |
| Telomere Testing |
| Therapeutic Eurythmy |
| Thought Field Therapy (TFT) <ul style="list-style-type: none"> Callahan Technique Training |
| Threshold Electrical Stimulation |
| Toftness Radiation Detector |
| Total Body Modification (TBM) |
| Traumeel Preparation |
| Trichuris Suis Ova Therapy |
| Urinary Organic Acids Profiling |
| Vascular Endothelial Cells (VEC) Therapy |
| Vector Point Cranial Therapy |

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| Technique / Procedure* |
|---|
| Vibrational Essences |
| Videonystagmography (VNG) (See the <i>Vestibular Rehabilitation (CPG 173 – S)</i> policy) |
| Virtual Reality – Motor-cognitive, semi-immersive virtual reality-facilitated gait training |
| Virtual reality technology to assist therapy |
| Webster Technique (See the <i>Webster Technique (CPG 99 – S)</i> policy) |
| Whitcomb Technique |
| Wurn Technique (Clear Passage Technique) |
| 714-X or 714X |

- 1 *Note: This is not an exhaustive list of all techniques and/or procedures that are not evidence-based practice.
- 2 All techniques and/or procedures utilized should be evaluated by the practitioner against the current accepted
- 3 scientifically valid clinical literature and the above defined criteria.