1 2 2	Clinical Practice Guideline:	Techniques and Procedures Not Widely Supported as Evidence-Based
3 4	Date of Implementation:	July 21, 2010
5 6	Product:	Specialty
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9 **GUIDELINES**

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

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

37 **PROCESS AND DEFINITIONS**

The ASH clinical procedure assessment process evaluates diagnostic and therapeutic procedures against professionally recognized standards of practice, current scientific evidence, and consensus of appropriate experts. The recommendations of the consensus panel are considered by ASH clinical committees when developing criteria, definitions, and processes to support clinical decision-making within ASH's clinical management system.

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1 2	When developing, reviewing, and approving clinical policy, ASH peer-review committees consider whether the technique/procedure:
3	• Is evidence-based with support from clinically relevant scientific information
4	which:
5	• Can be used to inform the diagnosis or treatment of a patient.
6	 Meets industry standard research quality criteria.
7	• Is adopted as credible by an ASH clinical peer review committee.
8	• Has been published in an acceptable peer-reviewed clinical science resource.
9 10	 Is established as clinically effective/established as having diagnostic utility by: Scientific information published in an acceptable peer-reviewed clinical science
11	resource.
12	• The consensus opinion of the Evidence Evaluation Committee (EEC) when
13	available.
14	• Is professionally recognized by:
15	o Inclusion in the educational standards accepted by the majority of the
16	professions' educational institutions.
17	• Wide acceptance and use of the practice.
18	• Recommendations for use made by healthcare practitioners practicing in the
19	relevant clinical area.
20	• Poses a health and safety risk.
21	• Is plausible or implausible.
22	• A belief, theory, or mechanism of health and disease that can be explained
23	within the existing framework of scientific methods, reasoning and available
24	knowledge is considered plausible.
25	• A treatment intervention or diagnostic procedure that requires the existence of
26	forces, mechanisms, or biological processes that are not known to exist within
27	the current framework of scientific methods, reasoning and available
28	knowledge is considered implausible.
29	• Is approved by the appropriate federal regulatory agency and being used for the
30	purpose defined in that approval (unless it is considered an off-label use or
31	otherwise meets the generally accepted standards of medical practice).
32	• This criterion applies to drugs, biological products, devices, and any other
33 34	product or procedure that must have final approval to market from the U.S. Food and Drug Administration (FDA) or any other federal government body
34 35	Tood and Drug Administration (TDA) of any other redefat government body
55	with authority to regulate the technology. However, approval by the FDA or
36	with authority to regulate the technology. However, approval by the FDA or other federal regulatory agency does not imply that the technology is
36 37	with authority to regulate the technology. However, approval by the FDA or other federal regulatory agency does not imply that the technology is automatically considered by ASH as medically necessary or the accepted

1 Other Considerations

- 2 **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.

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

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Technique / Procedure*		
ABO Blood Typing for Diagnosis and/or Treatment		
Actra-Rx		
Acutonics/Sonotonics		
Addictionology		
Advanced Biostructural Correction (ABC)		
Antineoplastons		
Antioxidant Function Testing (e.g., Spectrox TM)		
Apitherapy		
Applied Kinesiology (AK)		
Aromatherapy		
Ashiatsu Oriental Bar Therapy		
Aura Healing		
Auto-Urine Therapy (or Urine Therapy)		
Autogenous Lymphocyctic 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		
Carbon Dioxide Therapy		

Technique / Procedure*

Cari-Loder Regimen (lofepramine plus phenylalanine with B12)

Cellular Therapy

Chelation Therapy for Atherosclerosis

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

Cupping

Directional Non-Force Technique (DNFT)

Dry Hydrotherapy/Aquamassage/Hydromassage

Dry Needling (not acupuncture)

Ear Candling

Electro-Meridian Diagnosis Category:

- 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 and Soft Tissue Wounds

Fasting

Force Recording and Analysis System (FRAS)

Fresh Cell Therapy

Functional Intracellular Analysis, also known as:

- Essential Metabolic Analysis;
- Intracellular Micronutrient Analysis;
- Leukocyte Nutrient Analysis; and/or Micronutrient Analysis

Gemstone and/or Crystal Therapy

Hair Mineral Analysis

Holistic Kinesiology

Immuno-Augmentive Therapy (IAT)

Infrasonic/Infrasonic Therapy

Insulin Potentiation Therapy

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Technique / Procedure*	
Intensive Model of Therapy	
Intracellular Nutrient Analysis	
Intravenous Micronutrient Therapy (Myers' Cocktail)	
Intravenous Nutrient Therapy	
Inversion Therapy	
Iridology	
Iscador (Mistletoe)	
Jaffe-Mellor Technique (JMT)	
Kelley/Gonzalez Therapy	
Laetrile	
Laser Therapy	
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, Compreher	nsive full
body computer-based	
Matrix Repatterning / Energetics	
MEDEK Therapy	
Medicinal Mushrooms	
Megavitamin Therapy (Orthomolecular Medicine)	
Mesotherapy	
Micronutrient Panel Testing	
Mistletoe (Iscador)	
MTH-68/H Vaccine	
Moxibustion - Direct	
Nambudripad's Allergy Elimination Technique (NAET®)	
Needle Implants (Intradermal Needles, Ear tacks, etc.)	
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	
Non-invasive Interactive Neurostimulation (e.g., InterX®- all types)	
Organ/Visceral Manipulation	
Organic Acid Testing	
Organic Acid Testing Ortho-Bionomy	
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Technique / Procedure*
Peat Therapies
• Balneotherapy
Phage Therapy 12
Polarity Therapy (Energetic Healing)
(Poon's) Chinese Blood Cleaning
Prolonged Fasting Programs
Purging
Prolotherapy
Radionics
Reflexology
Regenerative Medicine (Stem Cell Treatments, Platelet-rich Plasma Injections)
Regenokine Therapy
Reiki
Remote therapeutic monitoring
Rife Therapy/Rife Machine
Sacro-Occipital Technique (SOT)TM
Sarapin Injections
Shark Cartilage Products
SonoKinesthesia Treatment
Surrogate Testing
Therapeutic Touch Therapy
Telomere Testing
Therapeutic Eurythmy
Thought Field Therapy (TFT)
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
Vibrational Essences
Videonystagmography (VNG)
Virtual Reality – Motor-cognitive, semi-immersive virtual reality-facilitated gait
training
Virtual reality technology to assist therapy
Webster Technique
Whitcomb Technique

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Technique / Procedure*

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.

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