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

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GUIDELINES

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

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

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.

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

- Is evidence-based with support from clinically relevant scientific information which:
  - Can be used to inform the diagnosis or treatment of a patient.
  - Meets industry standard research quality criteria.
  - Is adopted as credible by an ASH clinical peer review committee.
  - Has been published in an acceptable peer-reviewed clinical science resource.
- Is established as clinically effective/established as having diagnostic utility by:
  - Scientific information published in an acceptable peer-reviewed clinical science resource.
  - The consensus opinion of the Evidence Evaluation Committee (EEC) when available.
- Is professionally recognized by:
  - Inclusion in the educational standards accepted by the majority of the professions' educational institutions.
  - Wide acceptance and use of the practice.
  - Recommendations for use made by healthcare practitioners practicing in the relevant clinical area.
- Poses a health and safety risk.
- Is plausible or implausible.
  - A belief, theory, or mechanism of health and disease that can be explained within the existing framework of scientific methods, reasoning and available knowledge is considered plausible.
  - A treatment intervention or diagnostic procedure that requires the existence of forces, mechanisms, or biological processes that are not known to exist within the current framework of scientific methods, reasoning and available knowledge is considered implausible.
- Is approved by the appropriate federal regulatory agency and being used for the purpose defined in that approval (unless it is considered an off-label use or otherwise meets the generally accepted standards of medical practice).
  - This criterion applies to drugs, biological products, devices, and any other 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 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 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*
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 *Ashiatsu Oriental Bar Therapy (CPG 82 –S)* clinical practice guideline)
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)

Technique / Procedure*
Bovine Cartilage Products
Carbon Dioxide Therapy
Cari-Loder Regimen (lofepramine plus phenylalanine with B12)
Cellular Therapy
Chelation Therapy for Atherosclerosis (See the *IV Chelation Therapy (CPG 104 –S*) clinical practice guideline)
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 *CranioSacral Therapy (CST) (CPG 35 –S)* clinical practice guideline)
Cupping (See the *Instrument-Assisted Soft Tissue Mobilization (CPG 89-S)* clinical practice guideline)
Directional Non-Force Technique (DNFT)
Dry Hydrotherapy/Aquamassage/Hydromassage
Dry Needling (not acupuncture) (See the *Dry Needling (CPG 178 – S)* clinical practice guideline)
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
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

Technique / Procedure*
Hair Mineral Analysis (See the *Hair Mineral Analysis – Nutritional Management (CPG 103 - S)* clinical practice guideline)
Holistic Kinesiology
Immuno-Augmentive Therapy (IAT)
Infrasonic/Infrasonic Therapy
Insulin Potentiation Therapy
Intensive Model of Therapy (See the *Intensive Model of Therapy (CPG 286 –S)* clinical practice guideline)
Intracellular Nutrient Analysis
Intravenous venous Micronutrient Therapy (Myers' Cocktail)
Intravenous Nutrient Therapy
Inversion Therapy (See the *Inversion Therapy (CPG 107 – S)* clinical practice guideline)
Iridology
Iscador (Mistletoe)
Jaffe-Mellor Technique (JMT)
Kelley/Gonzalez Therapy
Laetrile
Laser Therapy (See the *Laser Therapy (CPG 30 – S)* clinical practice guideline)
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 *MEDEK Therapy (CPG 276 –S)* clinical practice guideline)
Medicinal Mushrooms
Megavitamin Therapy (Orthomolecular Medicine)
Mesotherapy
Micronutrient Panel Testing
Mistletoe (Iscador)
MTH-68/H Vaccine
Moxibustion – Direct (See the *Moxibustion CPG 48 – S)* clinical practice guideline)
Nambudripad's Allergy Elimination Technique (NAET®)
Needle Implants (Intradermal Needles, Ear tacks, etc.) (See the *Intradermal Needles and Ear Tacks (CPG 50 –S*) clinical practice guideline)
Network Spinal Analysis (NSA)
Neural Therapy
Neuro Emotional Technique (NET)

Technique / Procedure*
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) (See the *Non-invasive Interactive Neurostimulation (InterX®) (CPG 277- S)* clinical practice guideline)
Organ/Visceral Manipulation
Organic Acid Testing
Ortho-Bionomy
Peat Therapies • Balneotherapy
Phage Therapy
Polarity Therapy (Energetic Healing)
(Poon's) Chinese Blood Cleaning
Prolonged Fasting Programs
Purging
Prolotherapy (See the *Prolotherapy (CPG 94 – S)* clinical practice guideline)
Radionics
Reflexology
Regenerative Medicine (Stem Cell Treatments, Platelet-rich Plasma Injections)
Regenokine Therapy
Reiki
Rife Therapy/Rife Machine
Sacro-Occipital Technique (SOT)™ (See the *Sacro Occipital Technique (SOT) (CPG 96 - S)* clinical practice guideline)
Sarapin Injections (See the *Acupuncture Point Injection Therapy (APIT) (CPG 118 – S)* clinical practice guideline)
Shark Cartilage Products
SonoKinesthesia Treatment
Surrogate Testing
Therapeutic Touch Therapy (See the *Therapeutic Touch Therapy (CPG 106 – S)* clinical practice guideline)
Telomere Testing
Therapeutic Eurythmy
Thought Field Therapy (TFT) • Callahan Technique Training

Technique / Procedure*
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) (See the *Vestibular Rehabilitation (CPG 173 – S)* clinical practice guideline)
Virtual Reality – Motor-cognitive, semi-immersive virtual reality-facilitated gait training
Virtual reality technology to assist therapy
Webster Technique (See the *Webster Technique (CPG 99 – S)* clinical practice guideline)
Whitcomb Technique
Wurn Technique (Clear Passage Technique)
714-X or 714X

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