Evolent Clinical Guideline 1503 for Experimental, Unproven, or Investigational Services

Guideline Number: Evolent_CG_1503		
"Evolent" refers to Evolent Health LLC and Evolent Specialty Services, Inc. 		
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STATEMENT

General Information

It is an expectation that all patients receive care/services from a licensed clinician. All appropriate supporting documentation, including recent pertinent office visit notes, laboratory data, and results of any special testing must be provided. If applicable: All prior relevant imaging results and the reason that alternative imaging cannot be performed must be included in the documentation submitted.

Purpose

To provide a listing of procedures or services considered experimental, investigational, or unproven provided by any physical medicine practitioner‡.

Special Note

This policy lists the procedures considered experimental, or investigational provided by any physical medicine practitioner‡.

NOTE: Services listed in the policy are not eligible for reimbursement.

Coverage

If there is inconsistency between this medical policy and the terms of an enrollee's benefit plan, the terms of the enrollee's benefit plan supersede this policy.

NOTE: Coverage is subject to the terms of an enrollee's benefit plan

SERVICES

Defined

Experimental and investigational services (treatment, service, procedure, supply, device, or drug) are not recognized as standard clinical care for the condition (disease, illness, or injury) when scientific evidence to support its use is insufficient.

A service, procedure, or supply includes but is not limited to:

- Diagnostic service
- Treatment
- Facility
- Equipment or device

NOTE: This organization will determine whether a service, procedure, or supply is considered experimental and investigational, based upon reliable scientific methodology published in credible peer-reviewed journals or expert opinion from national and international professional medical organizations in the absence of definitive data.

Criteria

A service is considered experimental/investigation if **ANY** of the following criteria is met:

- A service, treatment, procedure, supply, device, or drug requiring appropriate government regulatory bodies approval does **NOT** have final approval (e.g., the Food and Drug Administration)
    - Restricted market approval for use in the treatment of a specified condition (not substituted for final approval)
    - Interim step in the regulatory process (not substituted for final approval)
- Insufficient or inconclusive evidence of the service, procedure, or supply
    - To evaluate the therapeutic value
    - On the beneficial effect on health outcomes
    - Is not as beneficial as an established alternative
    - When used in a non-investigational setting the service, procedure, or supply has a beneficial effect on health outcomes as any established alternatives

Experimental and Investigational Services

Experimental and investigational services listing (**non-exclusive list**):

- Advanced BioStructural Correction™ (ABC™)
- Alphabiotics
- Applied Kinesiology (including subfields)
- Applied Spinal Biomechanical Engineering
- Bio-Energetic Synchronization Technique (B.E.S.T)
- Blood Flow Restriction Training
- Chiropractic Biophysics (CBP, Clinical Biomechanics of Posture, CBP Mirror Image Technique)
- Chiropractic services directed at controlling progression and/or reducing scoliosis, including but not limited to the SpineCor brace and CLEAR scoliosis treatment
- Coccygeal Meningeal Stress Fixation
- Cold Laser Therapy
- Computerized muscle testing or analysis
- Cupping
- Craniosacral Therapy (CST, including the Upledger Technique)
- Directional Non-force Technique
- Dry Needling
- Hako-Med electrotherapy (horizontal electrotherapy)
- High-density surface electromyography (HD-sEMG), surface scanning EMG, paraspinal surface EMG, or macro EMG Hippotherapy (e.g., evaluating low back pain, thoracolumbar segmental abnormalities, soft tissue injury, intervertebral disc disease, nerve root irritation, or scoliosis)
- Impulse adjusting instrument

- Intersegmental traction and Autotraction
- Kinesio taping (Elastic Therapeutic Taping)
- Live Cell Analysis or hair analysis
- Manipulation under Anesthesia (MUA)
- Moire Contourographic Analysis
- Nambudripad's Allergy Elimination Technique (NAET)/ other Allergy Testing
- National Upper Cervical Chiropractic Association (NUCCA technique)/Grostic technique
- Network Chiropractic, Neuro Emotional Technique (NET)
- Neural Organizational Technique, Contact Reflex Analysis (CRA), Whole System Scan
- Neurocalometer, Nervo-Scope, Nerve Conduction Velocity, Surface EMG, Paraspinal Electromyography, Spinoscopy or other nerve conduction testing for non-specific neck and back pain
- Neurophysiologic Pain Profile (NPP), spine matrix scan (lumbar matrix scan)
- Nimmo Receptor-Tonus method
- Pettibon, including, but not limited to wobble chair/board treatment and posture pump
- Preventive Care, Corrective Care (chiropractic services)
- Pro-Adjuster
- Sacro Occipital Technique, Neurocranial Restructuring (NCR), Cranial Manipulation
- Sound Assisted Soft Tissue mobilization
- Spinal Diagnostic Ultrasound
- Repeat imaging to determine the progress of conservative treatment
- Thermography
- Treatment for brachioradial pruritis
- Vascular Studies, including, but not limited to, Doppler ultrasound analysis and **plethysmography**
- VAX-D, Lordex, LTX3000, DRX-9000, DRS (Decompression Reduction Stabilization System), or other back traction devices charged at a higher rate than mechanical traction (97012)
- Whole Body Vibration (WBV), Vibration Plate, Vibration Therapy
- Any lab work for which the office is not CLIA Certified or falls outside of the scope of practice, including, but not limited to drug testing, therapeutic drug assays, and organ or disease-oriented panels

Services Exceptions (Possibly Covered Under Another Service)

- Whole body vibration as a treatment for low back pain (LBP) evidence remains

equivocal

- Low level laser therapy could be an effective method for relieving pain in non-specific chronic low back pain [1]

NOTE: No significant treatment effect was identified for disability scores or spinal range of motion outcomes. Laser therapy combined with exercise provides better short-term relief of low back pain than either therapy alone. [2] No short-term benefit of laser therapy when compared with exercise alone. [2]

Plethysmography

- Plethysmography is one diagnostic modality for the conditions listed below or as an initial evaluation to determine the need for venography or arteriography
  - Chronic venous disease [3,4]
  - Arterial occlusive disease [5]
  - Evaluating total lung capacity and residual volume (Body Plethysmography/Pulmonary Function Test) [6]

NOTE: Since treatment of cardiovascular and lung conditions falls outside of the scope of chiropractic, patients should be referred for testing if these conditions are suspected.

Election of Services by Member

- If an experimental, unproven, or investigational service are to be provided, the practitioner will inform the member, in writing, that such services will be the member's responsibility
  - No services are to be performed in lieu of an appropriate examination or without consideration of an appropriate referral
- There is limited scientific evidence that the use of experimental, investigational, and unproven services provides a more accurate diagnosis, nor do they result in an improved clinical outcome
- For member exclusions or limitations refer to the enrollee's Certificate of Coverage or Summary Plan Description

Future Considerations

Removal of a service from the Experimental and Investigations Policy

- A review of the current literature will be evaluated annually to determine if there is additional evidence in support of any of the services listed under this policy (governmental regulatory bodies approval and scientific evidence)
- Scientific evidence must demonstrate the final conclusions pertaining to a treatment are based upon sound scientific study methodology published in credible, peer reviewed journals following a hierarchy of reliable evidence is used:
  - Systematic reviews or Meta analyses of randomized controlled trials
  - Technology assessments
  - Randomized Controlled Trials
  - Cohort studies

- Case-Control studies
- National and International Professional Medical Societies consensus (in absence of definitive scientific data)

NOTE: reliable evidence comes from well designed, high quality, double-blinded studies and not from personal professional opinions or personal choice for the standard of practice

- Services must be proven safe and effective:
  - Safety
    - Is the potential benefit superior to the potential harm
  - Health Outcomes
    - Superior or comparable to the established alternatives
  - Patient Management
    - Does the service improve clinical decision making
  - Clinical Performance
    - Is the reliability and predictive value of the service equal or superior to the current gold standard for the service
  - Cost-effectiveness
    - Is the service equal to or lower cost than established treatments that produce similar outcomes

NOTE: If the service appears to be safe and cost-effective, this organization will present these results to our health plan partners for consideration of coverage and/or payment. Final authority for such coverage determinations rests with the health plan.

CODING AND STANDARDS

Applicable Lines of Business

☒	CHIP (Children's Health Insurance Program)
☒	Commercial
☒	Exchange/Marketplace
☒	Medicaid
☒	Medicare Advantage

BACKGROUND

Health Care Providers

‡A qualified licensed health care providers (chiropractors, physical therapists, occupational therapists, speech language pathologist, physician assistants, speech language pathologist assistants, physical therapist assistants, and occupational therapy assistants) by education, training, and licensure/regulation performs a professional service within his/her scope of practice and reports to health professional boards.

POLICY HISTORY

Date	Summary
November 2024	• This guideline replaces Evolent_CG_601 Experimental, Unproven, or Investigational Services • Removed the CPT Codes section within Coding • Editorial changes to match the formatting and layout of the Evolent template • Corrected ‘Resistance’ to ‘Restriction’ for Blood Flow Restriction Training in the Indications section • Clarified language regarding Plethysmography within the “Service Exceptions” section
December 2023	• Removed; Services Exceptions – Ultrasound: as ultrasound is not applicable to therapy services • Editorial changes-sections adjusted/moved for better reading flow • Updated References

LEGAL AND COMPLIANCE

Guideline Approval

Committee

Reviewed / Approved by Evolent Specialty Clinical Guideline Review Committee

Disclaimer

Evolent Clinical Guidelines do not constitute medical advice. Treating health care professionals are solely responsible for diagnosis, treatment, and medical advice. Evolent uses Clinical Guidelines in accordance with its contractual obligations to provide utilization management. Coverage for services varies for individual members according to the terms of their health care coverage or government program. Individual members’ health care

coverage may not utilize some Evolent Clinical Guidelines. A list of procedure codes, services or drugs may not be all inclusive and does not imply that a service or drug is a covered or non-covered service or drug. Evolent reserves the right to review and update this Clinical Guideline in its sole discretion. Notice of any changes shall be provided as required by applicable provider agreements and laws or regulations. Members should contact their Plan customer service representative for specific coverage information.

REFERENCES

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