| National Imaging Associates, Inc. | | |
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| Clinical guidelines<br>EXPERIMENTAL, UNPROVEN, OR INVESTIGATIONAL SERVICES | Original Date:<br>Page 1 of 13 | November 2, 2015 |
| Physical Medicine – Clinical Decision Making | Last Review Date: | June 2017 |
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## Policy Statement

This policy will be used to provide a listing of procedures considered experimental, investigational by any physical medicine practitioner. Services listed in the policy are not eligible for reimbursement.

Initial Clinical Reviewers (ICRs) and Physician Clinical Reviewers (PCRs) must be able to apply criteria based on individual needs and based on an assessment of the local delivery system.

## Purpose

To provide a listing of procedures considered experimental, investigational, or unproven services by any physical medicine practitioner, including chiropractors, physical therapists, occupational therapists, and speech language pathologists.

## Scope

Clinical Management, Coding, Customer Service, Claims and Contracting.

## Coverage

Coverage is subject to the terms of an enrollee's benefit plan. To the extent there is any inconsistency between this medical policy and the terms of an enrollee's benefit plan, the terms of the enrollee's benefit plan documents will always control. Investigational services are not covered under enrollee's health plan.

## Definition

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

1. The services, procedures or supplies requiring Federal or other Governmental body approval, such as drugs and devices, do not have unrestricted market approval from the Food and Drug Administration (FDA) or final approval from any other governmental regulatory body for use in treatment of a specified condition. Any approval that is granted as an interim step in the regulatory process is not a substitute for final or unrestricted market approval.

2. There is insufficient or inconclusive medical and scientific evidence to evaluate the therapeutic value of the service, procedure, or supply.

3. There is inconclusive medical and scientific evidence in peer-reviewed medical literature that the service, procedure, or supply has a beneficial effect on health outcomes.

4. The service, procedure, or supply under consideration is not as beneficial as any established alternatives.

5. There is insufficient information or inconclusive scientific evidence that, when used in a non-investigational setting, the service, procedure, or supply has a beneficial effect on health outcomes or is as beneficial as any established alternatives.

Experimental and investigational services include the use of a service, procedure, or supply that is not recognized as standard clinical care for the condition, disease, illness, or injury being treated. A service, procedure, or supply includes, but is not limited to the diagnostic service, treatment, facility, equipment, or device. This organization will determine whether a service, procedure, or supply is considered experimental and investigational.

The following is a partial listing of experimental and investigational services:

- Advanced BioStructural Correction (ABC)
- Alphabiotics
- Applied Kinesiology or any of its derivations
- Applied Spinal Biomechanical Engineering
- BioEnergetic Synchronization Technique (B.E.S.T)
- Chiropractic Biophysics (CBP, Clinical Biomechanics of Posture, CBP Mirror Image Technique)
- Coccygeal Meningeal Stress Fixation
- Cold Laser Therapy
- Computerized muscle testing or analysis
- Craniosacral Therapy (CST)
- Directional Non-force Technique
- Hako-Med electrotherapy (horizontal electrotherapy)
- Hippotherapy
- 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, NeuroEmotional Technique (NET)
- Neurocalometer, Nervoscope, Nerve Conduction Velocity, Surface EMG, Paraspinal Electromyography, Spinoscopy or other nerve conduction testing for non-specific neck and back pain
- Neural Organizational Technique, Contact Reflex Analysis (CRA), Whole System Scan
- Nimmo Receptor-Tonus method

- Pettibon, including, but not limited to wobble chair/board treatment and posture pump
- Preventive Care, Maintenance Care, Corrective Care
- Pro-Adjuster
- Sacro Occipital Technique, Neurocranial Restructuring (NCR), Cranial Manipulation
- Sound Assisted Soft Tissue mobilization
- Spinal Diagnostic Ultrasound
- Chiropractic services directed at controlling progression and/or reducing scoliosis, including but not limited to the SpineCor brace and CLEAR scoliosis treatment
- Repeat imaging to determine the progress of conservative treatment
- Thermography
- Upledger Technique
- 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
- Treatment for brachioradial pruritis
- Dry Needling

Professional societies have published position statements concluding that diagnostic spinal ultrasound is investigational for non-operative spinal and paraspinal conditions in adults. The 2014 policy statement of the American Institute of Ultrasound in Medicine indicates: "There is insufficient evidence in the peer-reviewed medical literature establishing the value of non-operative spinal/paraspinal ultrasound in adults (for study of intervertebral discs, facet joint and capsules, central nerves and fascial edema, and other subtle paraspinous abnormalities) for screening, diagnostic evaluation, including pain or radiculopathy syndromes, and for monitoring of therapy has no proven clinical utility."

There is insufficient peer-reviewed published scientific evidence that computerized muscle testing leads to better patient outcomes. There is insufficient evidence to support any specific therapeutic effect of craniosacral therapy. While there is emerging evidence for the effectiveness of whole body vibration in treating some medical conditions, the evidence for whole body vibration as a treatment for LBP remains equivocal.

A 2015 systematic review found that that low level laser therapy is an effective method for relieving pain in non-specific chronic low back pain patients. However, no significant treatment effect was identified for disability scores or spinal range of motion outcomes. Yelden and colleagues concluded that there is no fundamental difference between LLLT and placebo LLLT when they are supplementing an exercise program for rehabilitation of patients with shoulder impingement syndrome (Yelden, 2009). Ay and colleagues found no differences between laser and placebo laser treatments on pain severity and functional capacity in patients with acute and chronic low back pain caused by lumbar disc herniation

(Ay, 2010). The Blue Cross and Blue Shield Association Technology Evaluation Center (2010) concluded that LLLT for either carpal tunnel syndrome or for chronic neck pain does not meet the Blue Cross and Blue Shield Association Technology Evaluation Center (TEC) criteria. Furthermore, the Work Loss Data Institute's clinical practice guideline on "Carpal tunnel syndrome" (2011) does not recommend LLLT as a therapeutic option. The effectiveness of LLLT in reducing acute and chronic neck pain was examined in 2013. The authors concluded that this systematic review provided inconclusive evidence because of significant between-study heterogeneity and potential risk of bias. They stated that the benefit seen in the use of LLLT, although statistically significant, does not constitute the threshold of minimally important clinical difference (Kadhim-Saleh, 2013). The best available current evidence does not support the effectiveness of low level laser therapy as a therapy for patients with knee osteoarthritis (Huang, 2015).

There is insufficient evidence to support the clinical value of the Pettibon System. Posture Pump is deemed experimental and investigational because the effectiveness of this device has not been proven by adequate scientific studies, published in peer-reviewed scientific journals. There is insufficient evidence to support the clinical value of the Therapeutic (Wobble) Chair/Board.

The appropriateness and effectiveness of chiropractic manipulation as a preventive or maintenance therapy has not been established by clinical research and is not covered.

Thermography has not been shown to provide sufficient reliable characterizing information about neurologic dysfunction or deficit to accept it as a proven evaluative procedure for the clinical diagnosis or characterization of: neck or back pain; musculoskeletal pain; entrapment neuropathy; headache; or transient cerebral ischemia and stroke.

High-density surface electromyography (HD-sEMG), surface scanning EMG, paraspinal surface EMG, or macro EMG are considered experimental and investigational as a diagnostic test for evaluating low back pain or other thoracolumbar segmental abnormalities, such as soft tissue injury, intervertebral disc disease, nerve root irritation and scoliosis, and for all other indications because the reliability and validity of these tests have not been established. Surface EMG devices are also experimental and investigational for diagnosis and/or monitoring of nocturnal bruxism and all other indications because the reliability and validity of these tests have not been demonstrated. The Neurophysiologic Pain Profile (NPP) and the spine matrix scan (lumbar matrix scan) are considered experimental and investigational because the reliability and validity of these tests has not been established.

There is insufficient evidence to conclude that nerve conduction studies are beneficial for health outcomes in patients with non-specific neck or back pain. Non-invasive automatic or portable nerve conduction monitoring systems that test only distal motor latencies and conduction velocities are unproven and not medically necessary for the purpose of electrodiagnostic testing.

Plethysmography is used to diagnose deep vein thrombosis and arterial occlusive disease. Plethysmography is used as the sole diagnostic modality for these conditions or as an initial evaluation to determine the need for venography or arteriography. Body Plethysmography evaluates total lung capacity and residual volume. 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.

## Procedure

1. **Guidelines**
   a. If such services are to be provided, the practitioner will inform the member, in writing, that such services will be the member's responsibility. None of these services are to be performed in lieu of an appropriate examination or without consideration of an appropriate referral.
   b. There is limited scientific evidence that the use of experimental, investigational and unproven services provides an improved or more accurate diagnosis, nor do they result in an improved clinical outcome.
   c. Scientific literature will continue to be reviewed and any significant changes in published literature will be taken into consideration for modification of this policy.

2. **Exclusions/Limitations (not limited to)**
   Refer to enrollee's Certificate of Coverage or Summary Plan Description.

3. **Removal of a service from the Experimental and Investigations Policy**
   At least annually, a review of the current literature will be evaluated to determine if there is additional research in support of any of the services listed under this policy. This evaluation will include the following criteria:
   - Safety – Is the potential benefit superior to the potential harm?
   - Health Outcomes – Is there evidence the service will provide, at minimum, equal outcomes and at best, superior outcomes to currently available services?
   - Patient Management – Will the service improve clinical decision making?
   - Clinical Performance – Is the reliability as well as predictive value of the service equal or superior to the current "gold standard" for such services?
   - Cost-effectiveness – Is the service equal to or lower cost than currently utilized services for similar diagnosis and treatment?

All criteria will be based on peer-reviewed scientific literature and internationally and nationally accepted and published guidelines. Peer-reviewed scientific studies must be published in or accepted for publication by medical journals meeting national requirements for scientific publication (http://www.icmje.org). The medical literature must meet the National Institutes of Health Library of Medicine for indexing (http://www.nlm.nih.gov). Medical journals that publish most of their scientific manuscripts by the editorial staff of a journal will not be considered for review. If the majority of funding for research is published by the device manufacturer or organization sponsoring a technique the results will not be considered for review.

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.

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