

<b>*National Imaging Associates, Inc.</b>	
<b>Clinical guidelines EXPERIMENTAL, UNPROVEN, OR INVESTIGATIONAL SERVICES</b>	<b>Original Date: November 2015</b>
<b>Physical Medicine – Clinical Decision Making</b>	<b>Last Revised Date: <del>December</del>August 2023<del>2</del></b>
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## Table of Contents

<b>GENERAL INFORMATION .....</b>	<b>2</b>
<b>STATEMENT .....</b>	<b>2</b>
PURPOSE .....	2
COVERAGE .....	2
<b>SERVICES .....</b>	<b>2</b>
DEFINED .....	2
CRITERIA .....	3
EXPERIMENTAL AND INVESTIGATIONAL SERVICES .....	4
SERVICES EXCEPTIONS (POSSIBLY COVERED UNDER ANOTHER SERVICE) .....	5
ELECTION OF SERVICES BY MEMBER .....	7
FUTURE CONSIDERATIONS .....	8
<b>BACKGROUND .....</b>	<b>9</b>
HEALTH CARE PROVIDERS .....	9
<b>POLICY HISTORY .....</b>	<b>10</b>
<b>REFERENCES .....</b>	<b>11</b>

## 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.*

### Policy Statement

This policy ~~will be used to list~~provides a listing of the procedures considered experimental, or investigational provided by any physical medicine practitioner<sup>‡</sup>.

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

### Purpose

To provide a listing of procedures or services considered experimental, investigational, or unproven provided services by any physical medicine practitioner<sup>‡</sup>, ~~including chiropractors, physical therapists, occupational therapists, and speech language pathologists.~~

### Coverage

~~To the extent there is any 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 ~~documents will always control~~supersedes this policy. ~~Investigational services are not covered under enrollee's health plan.~~

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

### Services Definition

#### Defined

Experimental and investigational services (treatment, include the use of a service, procedure, or supply, device, or drug) that are not recognized as standard clinical care for the condition, (disease, illness, or injury) being treated 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 services, treatment, procedures, or supply, device, or drugies requiring appropriate Federal or other Government regulatory bodies approval does NOT have final approval (e.g., the Food and Drug Administration), such as drugs and devices,
  - do not have unrestricted Restricted market approval from the Food and Drug Administration (FDA) or final approval from any other governmental regulatory body for use in the treatment of a specified condition (not substituted for final approval)
  - I. Any approval that is granted as an interim step in the regulatory process (not substituted for final approval) is not a substitute for final or unrestricted market approval.

### Insufficient or

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

○

○ On the beneficial effect on health outcomes

- 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.

○

Is not as beneficial as an established alternative

○

When used in a non-investigational setting The service, procedure, or supply under consideration is not as beneficial as any established alternatives.

- There is insufficient information or inconclusive scientific evidence that, when used in a non-investigational setting, t 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.~~

### **Experimental and Investigational Services**

~~The following is a partial listing of e~~Experimental and investigational services listing (non-exclusive list):~~;~~

- Advanced BioStructural Correction™ (ABC™)
- Alphabiotics
- Applied Kinesiology (including subfields or any of its derivations)<sup>4</sup>
- Applied Spinal Biomechanical Engineering
- Bio-Energetic Synchronization Technique (B.E.S.T.)<sup>2</sup>
- Blood Flow Resistance Training<sup>3-6</sup>
- Chiropractic Biophysics (CBP),<sup>7</sup> Clinical Biomechanics of Posture, CBP Mirror Image Technique<sup>8</sup>
- Chiropractic services directed at controlling progression and/or reducing scoliosis, including but not limited to the SpineCor brace<sup>9</sup> and CLEAR scoliosis treatment
- Coccygeal Meningeal Stress Fixation
- Cold Laser Therapy
- Computerized muscle testing or analysis
- Cupping<sup>10-13</sup>
- Craniosacral Therapy (CST),<sup>14</sup> including the Upledger Technique<sup>1</sup>
- Directional Non-force Technique<sup>15</sup>
- Dry Needling<sup>16</sup>
- Hako-Med electrotherapy (horizontal electrotherapy)<sup>17</sup>
- 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)<sup>18-24</sup>
- Impulse adjusting instrument
- Intersegmental traction and Autotraction<sup>25,26</sup>
- Kinesio taping<sup>27-34</sup> (Elastic Therapeutic Taping)
- Live Cell Analysis or hair analysis<sup>35,36</sup>
- Manipulation under Anesthesia (MUA)<sup>37,38</sup>
- Moire Contourographic Analysis<sup>39</sup>
- Nambudripad's Allergy Elimination Technique (NAET)/ other Allergy Testing<sup>40</sup>
- National Upper Cervical Chiropractic Association (NUCCA technique)<sup>41</sup> /-Groscopic technique

- Network Chiropractic, Neuro Emotional Technique (NET)<sup>42,43</sup>
- Neural Organizational Technique, Contact Reflex Analysis (CRA),<sup>44</sup> Whole System Scan
- Neurocalometer, Nervo-Scope, Nerve Conduction Velocity, Surface EMG,<sup>45</sup> Paraspinal Electromyography,<sup>46</sup> Spinoscopy or other nerve conduction testing for non-specific neck and back pain<sup>47,48</sup>
- Neurophysiologic Pain Profile (NPP), spine matrix scan (lumbar matrix scan)
- Nimmo Receptor-Tonus method<sup>49</sup>
- Pettibon, including, but not limited to wobble chair/board treatment and posture pump<sup>50-55</sup>
- Preventive Care, Corrective Care (chiropractic services)
- Pro-Adjuster
- Sacro Occipital Technique, Neurocranial Restructuring (NCR),<sup>56</sup> Cranial Manipulation
- Sound Assisted Soft Tissue mobilization<sup>57</sup>
- Spinal Diagnostic Ultrasound<sup>58</sup>
- Repeat imaging to determine the progress of conservative treatment
- Thermography<sup>59</sup>
- Treatment for brachioradial pruritis
- Vascular Studies, including, but not limited to, Doppler ultrasound analysis and plethysmography
- VAX-D,<sup>60</sup> 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),<sup>61-63</sup> 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 ~~to~~to drug testing, therapeutic drug assays, and organ or disease-oriented panels

### Services Exceptions (possibly covered under another service)

Ultrasound may, however, be used as a guidance modality for certain spinal injections [1]."<sup>64</sup>

~~NOTE: Professional societies have published position statements that diagnostic spinal ultrasound is investigational for non-operative spinal and paraspinal conditions in adults. 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 diagnostic evaluations of conditions involving the intervertebral disks, facet joints and capsules, and central nerves... [A]t this time, the use of ultrasound in diagnostic evaluations, screening, or monitoring of therapy for these conditions has no proven clinical utility and should be considered investigational [1]."~~

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

- ~~A 2015 systematic review<sup>65</sup> found that that low level laser therapy is an effective method for relieving pain in non-specific chronic low back pain [2] patients~~

~~**NOTE:** However, no significant treatment effect was identified for disability scores or spinal range of motion outcomes. Guidelines from the North American Spine Society (2020)<sup>66</sup> report there is fair evidence to suggest that laser therapy combined with exercise provides better short-term relief of low back pain than either therapy alone [3]. In addition, they report no short-term benefit of laser therapy when compared with exercise alone [3]. Current studies supported by larger sample sizes with longer follow-up was recommended. In a 2009 study, Yeldan and colleagues report no statistically significant differences between the placebo LLLT and LLLT groups on shoulder function in subacromial impingement syndrome.<sup>67</sup> 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 LDH [lumbar disc herniation].”<sup>68</sup> Furthermore, both a 2016 Cochrane review<sup>69</sup> and 2017 meta-analysis<sup>70</sup> report limited effectiveness of low level laser therapy in carpal tunnel syndrome management. A 2013 study examined the effectiveness of LLLT in reducing acute and chronic neck pain. The authors concluded, “This systematic review provided inconclusive evidence because of significant between-study heterogeneity and potential risk of bias. The benefit seen in the use of LLLT, although statistically significant, does not constitute the threshold of minimally important clinical difference.”<sup>71</sup> The best available current evidence does not support the effectiveness of low level laser therapy as a therapy for patients with knee osteoarthritis.<sup>65</sup>~~

~~Similarly, 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 the sole diagnostic modality for the listed conditions below or as an initial evaluation to determine the need for venography or arteriography
  - ~~is used to~~ Diagnose deep vein thrombosis [4] [5]<sup>72,73</sup>
  - ~~Diagnose a~~ and arterial occlusive disease [6].<sup>74</sup>
  - ~~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 [7].<sup>75</sup> (Body Plethysmography)

**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

### **Procedure**

### **Guidelines**

- If an experimental, unproven, or investigational ~~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.

- There is limited scientific evidence that the use of experimental, investigational, and unproven services provides ~~an improved or a~~ more accurate diagnosis, nor do they result in an improved clinical outcome.

~~For member Scientific literature will continue to be reviewed and any significant changes in published literature will be taken into consideration for modification of this policy.~~

- ~~eExclusions or l/Limitations (not limited to)~~
  - ~~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 ~~research evidence~~ in support of any of the services listed under this policy (governmental regulatory bodies approval and scientific evidence)
- ~~Scientific literature will continue to be reviewed and any significant changes in published literature will be taken into consideration for modification of this policy.~~ 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

~~This evaluation will include the following criteria:~~

- Services must be proven safe and effective;
  - 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 or comparable to the established alternatives outcomes to currently available services?~~



- 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 ~~currently utilized services for similar diagnosis and treatment?~~ established treatments that produce similar outcomes

~~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 standards for indexing (<https://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.~~

**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.

## **BACKGROUND**

### **Health Care Providers**

<sup>‡</sup>A qualified licensed health care providers (chiropractors, physical therapists, occupational therapists, speech language pathologist, physician assistants, speech language pathologist assistants, therapists, 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
<a href="#">December 2023</a>	<ul style="list-style-type: none"><li>• <a href="#">Removed; Services Exceptions – Ultrasound: as ultrasound is not applicable to therapy services</a></li><li>• <a href="#">Editorial changes-sections adjusted/moved for better reading flow</a></li><li>• <a href="#">Updated References</a></li></ul>
August 2022	<ul style="list-style-type: none"><li>• Removed “Maintenance Care” from the list of E &amp; I services</li><li>• References updated</li></ul>
December 2021	<ul style="list-style-type: none"><li>• Added “General Information” statement</li><li>• Reordered (in alphabetical order) the list of experimental and investigational services</li><li>• Added Blood Flow Resistance Training to list of E&amp;I services</li></ul>

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## Reviewed/Approved by NIA Clinical Guideline Committee

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