MEDX EXTENSION MACHINE
FOR NECK OR LOW BACK PAIN

Policy Number: 2015M0004A    Effective Date: July 1, 2015

Table of Contents:

<table>
<thead>
<tr>
<th>Table of Contents</th>
<th>Page:</th>
<th>Cross Reference Policy:</th>
</tr>
</thead>
<tbody>
<tr>
<td>POLICY DESCRIPTION</td>
<td>2</td>
<td>Spinal Cord Stimulator, 2014M0002B</td>
</tr>
<tr>
<td>COVERAGE RATIONALE/CLINICAL CONSIDERATIONS</td>
<td>2</td>
<td>Epidural Steroid Injections for Low Back Pain and Sciatica, 2012M0014A</td>
</tr>
<tr>
<td>BACKGROUND</td>
<td>2</td>
<td></td>
</tr>
<tr>
<td>REGULATORY STATUS</td>
<td>3</td>
<td></td>
</tr>
<tr>
<td>CLINICAL EVIDENCE</td>
<td>3</td>
<td></td>
</tr>
<tr>
<td>APPLICABLE CODES</td>
<td>4</td>
<td></td>
</tr>
<tr>
<td>REFERENCES</td>
<td>4</td>
<td></td>
</tr>
<tr>
<td>POLICY HISTORY/REVISION INFORMATION</td>
<td>7</td>
<td></td>
</tr>
</tbody>
</table>

INSTRUCTIONS:

“Medical Policy assists in administering UCare benefits when making coverage determinations for members under our health benefit plans. When deciding coverage, all reviewers must first identify enrollee eligibility, federal and state legislation benefit mandates, and the member specific Evidence of Coverage (EOC) document must be referenced prior to using the medical policies. In the event of a conflict, the enrollee's specific benefit document supersedes this Medical Policy. In the absence of benefit mandates that govern the service, procedure or treatment, or when the member’s EOC document is silent or not specific, medical policies help to clarify which healthcare services may or may not be covered. This Medical Policy is provided for informational purposes and does not constitute medical advice. In addition to medical policies, UCare also uses tools developed by third parties, such as the InterQual Guidelines®, to assist us in administering health benefits. The InterQual Guidelines are intended to be used in connection with the independent professional medical judgment of a qualified health care provider and do not constitute the practice of medicine or medical advice. Other Policies and Coverage Determination Guidelines may also apply. UCare reserves the right, in its sole discretion, to modify its Policies and Guidelines as necessary.”
POLICY DESCRIPTION:
This policy describes the use of Med-X, a computerized, active range of motion set of exercising machines for the purposes of evaluating strength and function of the lumbar and cervical spine, and providing therapy for back and neck pain. It is proposed that using this device during rehabilitation can improve range of motion and strengthen muscles. The rehabilitation program typically lasts 12 weeks.

COVERAGE RATIONALE / CLINICAL CONSIDERATIONS:
Published clinical evidence does NOT support the use of MedX lumbar/cervical extension for the treatment of back pain. The device is considered EXPERIMENTAL AND INVESTIGATIONAL for the treatment of any condition, due to inadequate evidence of safety and/or efficacy, in published peer reviewed literature. Therefore this health service is NOT MEDICALLY NECESSARY.

Clinical Considerations:
Clinical evidence does not support MedX for the purposes of evaluating and treating lumbar pain. There are neither adequate nor well-controlled studies that demonstrates MedX efficacy over other exercise programs.

- Therapy is to be administered only in the chronic stage of the disease (i.e., over 45 days post-injury).
- Patients must present with a history of failed traditional conservative modes of treatment (i.e. ultrasound, diathermy, electrical stimulation, massage, home exercises, etc.)
- Contraindications: Absolute and relative contraindications for the MedX machine include pregnancy, severe osteoporosis, recent and/or acute spinal fractures, infection or tumor, recent surgery, and metabolic bone disease.28
- Consensus guidelines that were issued by the developers of the MedX machine in 1995 advise that only clinicians certified in the use of the MedX machine at the University of Florida or the University California should deliver MedX machine services.17

BACKGROUND:
Back pain may originate from the vertebrae, intervertebral discs, spinal cord, nerve roots, facet joints, ligaments, muscles, and sacroiliac, atlanto-axial, and atlanto-occipital joints. Most back pain will resolve spontaneously or can be treated with conservative and noninvasive therapies, such as analgesics, anti-inflammatory drugs, muscle relaxants, exercise, physical therapy, immobilization, and trigger-point injections with local anesthetics. Other nonsurgical methods of treatment include the use of traction, chiropractic care with spinal manipulation, transcutaneous electrical stimulators, spinal orthotic devices, acupuncture, and thermal techniques. Surgery may be required for the conditions with underlying pathology as determined by radiological findings.

Various noninvasive treatments have been proposed for use as treatment of low back pain, including quantitative muscle testing and treatment devices, isokinetic testing and treatment devices, internal disc decompression devices, vertebral axial decompression devices (e.g., vertebral axial decompression [VAX-D] devices), and patient-operated spinal unloading devices e.g., LTX 3000™, Orthotrac™ Pneumatic Vest).
Most of these devices require special training of the clinician and, in some cases, certification, and are generally used by physical therapists as part of rehabilitation programs and are not typically used in a home setting.

The MedX lumbar/cervical extension machine is a device that can provide both functional muscle testing of the spine and spinal therapy. It provides resistance over a full range of isolated lumbar motion over a preselected, limited range. The machine is capable of setting isometric test points every three degrees within an individual’s range of motion. During the test, a computer software system plots the individual’s actual range of motion and strength in comparison to that of age- and gender-matched norms. In exercise mode, the compound weight stack can provide resistance from 10–400 foot pounds in increments of one foot pound. It is proposed that use of this device can specifically test the strength of the lumbar spine and, through rehabilitation, the device can strengthen muscles. The rehabilitation program typically lasts 12 weeks, with computerized strength and motion testing performed every four weeks.

**REGULATORY STATUS:**

1. **U.S. FOOD AND DRUG ADMINISTRATION (FDA):** MedX machines are regulated as class II devices that are subject to the FDA 510(k) approval process. The first MedX machine approval was issued September 14, 1989 for the MedX Rehabilitation Machine (K895236). Subsequent approvals were issued on January 2, 1990 for the MedX Cervical Extension Test & Rehabilitation Machine (K896553) and on July 3, 1991 for the MedX Machine (K911666).

   The MEDX Lumbar Extension machine received a Class II device approval from the FDA as an exerciser, measuring (e.g., exercise measuring equipment). Listing Date: 02-25-02.

2. **CENTERS FOR MEDICARE AND MEDICAID SERVICES (CMS):**

   Medicare does not cover MedX. A retired article (A26924) effective 5-28-2010, VaxD and MedX are considered - Not Proven Effective – and not covered by Medicare, due to insufficient scientific data to support a finding of significant benefits of this technique.

   Local Coverage Determinations (LCDs) for power traction devices do not exist at this time. (Accessed March 15, 2013)

3. **MINNESOTA DEPARTMENT OF HUMAN SERVICES (DHS):**

   Minnesota DHS does not have a policy statement regarding MedX in its Provider Manual or other specific provider references.

**CLINICAL EVIDENCE:**

**SUMMARY:** Results of these studies fail to provide adequate evidence that MedX therapy yields benefits that are comparable with those obtained with standard treatments for neck and back pain. Although three RCTs evaluated MedX therapy, two of these RCTs involved treatment of the control groups with spinal manipulation or vibration therapy, which do not seem to be widely accepted approaches to neck and back pain treatment. In the third RCT, the control group underwent a standard program of exercise therapy at home; however, this therapy was compared with an intensive, supervised program of MedX therapy. Differences in exercise intensity and supervision may have biased outcomes in favor of MedX therapy.
Despite this potential bias, MedX therapy was not associated with significantly better Oswestry Disability Index scores or any other long-term benefits. Furthermore, MedX therapy was not found to provide benefits greater than those provided by vibration therapy or by spinal manipulation combined with an exercise program that used no sophisticated exercise machines. Further studies are needed to determine whether MedX therapy provides benefits that equal or exceed those provided by comparable standard treatment approaches. No safety issues were identified for the MedX machine, in the reviewed studies. In one clinical trial of the MedX machine for chronic neck pain, increases in neck pain or headache were seen in a similar proportion of patients receiving MedX, spinal manipulation therapy (SMT) or SMT combined with traditional exercise.

**APPLICABLE CODES:**

The Current Procedural Terminology (CPT®) codes and HCPCS codes listed in this policy are for reference purposes only. Listing of a service or device code in this policy does not imply that the service described by this code is a covered or non-covered health service. The inclusion of a code does not imply any right to reimbursement or guarantee claims payment. Other medical policies and coverage determination guidelines may apply.

<table>
<thead>
<tr>
<th>HCPCS Codes</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>E1399</td>
<td>Durable medical equipment, miscellaneous</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>CPT® Codes</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>95831</td>
<td>Muscle testing, manual (separate procedure) with report; extremity (excluding hand) or trunk</td>
</tr>
<tr>
<td>95851</td>
<td>Range of motion measurements and report (separate procedure); each extremity (excluding hand) or each trunk section (spine)</td>
</tr>
<tr>
<td>97001</td>
<td>Physical therapy evaluation</td>
</tr>
<tr>
<td>97012</td>
<td>Application of a modality to one or more areas; traction, mechanical</td>
</tr>
<tr>
<td>97110</td>
<td>Therapeutic procedure, one or more areas, each 15 minutes; therapeutic exercises to develop strength and endurance, range of motion and flexibility</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>ICD-9 Codes</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Investigational for all diagnoses</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>ICD-10 Codes</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Investigational for all diagnoses</td>
</tr>
</tbody>
</table>

CPT® is a registered trademark of the American Medical Association.

REFERENCES:


POLICY HISTORY:

<table>
<thead>
<tr>
<th>DATE</th>
<th>ACTION/DESCRIPTION</th>
</tr>
</thead>
<tbody>
<tr>
<td>03/28/2013</td>
<td>Quality Improvement Advisory and Credentialing Council (QIACC).</td>
</tr>
<tr>
<td>11/15/2013</td>
<td>Published to UCare.org</td>
</tr>
</tbody>
</table>
| 07/01/2015 | Policy Update:
|            | • Added applicable ICD-9/ICD-10 information to the Coding Section.                  |
|            | • No change to policy statements. References and rationale updated.                |
|            | • Policy identification number updated to 2015M0012A.                              |