I. Quantitative Muscle Testing Devices

Aetna considers the use of quantitative muscle testing devices (e.g., MedX Lumbar and Cervical Extension Devices, Isostation B-200 Lumbar Dynamometer, Kin-Com Physical Therapy Isokinetic Equipment, Cybex Back System, Biodex System 3, JTECH Tracker Freedom Wireless Muscle Testing) experimental and investigational when used for muscle testing because there is insufficient evidence that use of these devices improves the assessment of muscle strength over standard manual strength testing such that clinical outcomes are improved.

Note: No additional reimbursement is provided for performing manual muscle testing using hand-held dynamometers (e.g., Lafayette Manual Muscle Test, Nicholas Manual Muscle Tester, Hoggan...
Dynamometer). The use of the hand-held dynamometer is considered integral to the manual muscle testing and is not separately reimbursed.

**Note:** Isokinetic devices (e.g., Biodex, Cybex, and Kin-Com) and other exercise and testing machines (e.g., Isostation B-2000 and MedX) are considered acceptable alternatives for provision of medically necessary exercise in physical therapy. In addition to use in muscle testing, the MedX and other machines have also been used for administering exercise therapy. These devices can be used as exercise machines for administering physical therapy. However, these particular brands of exercise devices have not been proven to be superior to standard brands of exercise equipment (e.g., Nautilus, etc.) when used for administering physical therapy.

**II. Orthotrac Pneumatic Vest**

Aetna considers the Orthotrac pneumatic vest, a non-surgical spinal treatment device that has been promoted to relieve back pain of various etiologies, experimental and investigational.

The Orthotrac is an inflatable pneumatic vest that has been used to relieve back pain from a variety of causes (e.g., herniated disc, spinal stenosis, facet syndrome, spondylolysis, etc). There is insufficient peer-reviewed published clinical evidence of the effectiveness of the Orthotrac pneumatic vest in relieving back pain.

**III. Back School**

Aetna considers back school medically necessary for the treatment of persons with chronic or recurrent back pain, when such a program is prescribed by the member’s doctor and the program is conducted by a physical therapist or other
appropriate recognized healthcare professional.

CPB 0325 - Physical Therapy Services
See (../300_399/0325.html).

Note: Back school for occupational purposes may be excluded from coverage.
See CPB 0250 - Occupational Therapy Services (0250.html);
CPB 0198 - Work Hardening Programs and (../100_199/0198.html)
Please check benefit plan descriptions for details.

IV. Spinal Adjusting Instruments

See CPB 0107 - Chiropractic Services (../100_199/0107.html).

V. Khan Kinetic Treatment

Aetna considers the Khan Kinetic Treatment experimental and investigational for the treatment of back pain or any other indications because its effectiveness has not been established.

VI. Experimental and Investigational Interventions

Aetna considers the following interventions experimental and investigational for the treatment of back pain because their effectiveness has not been established:

• Auricular acupressure
• Cupping therapy
• Dr. Ho's 2-in-1 Decompression Belt
• Gabapentinoids (e.g., gabapentin and pregabalin) (excluding fibromyalgia indication).
See also
CPB 0011 - Electrical Stimulation for Pain
(../1_99/0011.html)
,
CPB 0016 - Back Pain - Invasive Procedures
(../1_99/0016.html)
,
CPB 0132 - Biofeedback (../100_199/0132.html)
,
CPB 0135 - Acupuncture (../100_199/0135.html),
CPB 0180 - Vertebral Axial Decompression
(../100_199/0180.html)
,
CPB 0204 - Manipulation Under General Anesthesia
(0204.html)
,
CPB 0207 - Prolotherapy (0207.html),
and
CPB 0569 - Lumbar Traction Devices (../500_599/0569.html)
.

Background

Quantitative Muscle Testing Devices

Muscle strength testing may be used to determine bilateral differences in strength or other differences in patient resistance. These differences may be characterized by the experienced examiner based on various technologies, i.e., manual, mechanized and computerized muscle testing. These changes may be a result of alterations of function at various levels of the neuromuscular system and/or any other system related to the patient. Computerized muscle testing has been used in clinical research to quantify muscle strength and enables the investigator to produce comparison reports, quantifying patient response to rehabilitation and therapy. However, manual muscle testing is sufficiently reliable for clinical practice. There is insufficient peer-reviewed published scientific evidence that computerized muscle testing leads to better patient outcomes.
The MedX lumbar/cervical extension machine has been proposed for use for isometric and isokinetic muscle testing and rehabilitation in persons with low back pain (LBP) and/or neck pain. The MedX lumbar/cervical extension device has not been adequately validated as a test of isometric and isokinetic muscle strength in persons with back or neck pain. In addition, the MedX machine has not been shown to be superior to any other particular brand of exercise equipment when used for administering physical therapy. A technology assessment of the MedX Lumbar Extension Machine for the treatment of LBP by the Washington State Department of Labor and Industries (2003) concluded: “The evidence suggests that MedX may help to increase lumbar muscle strength. However, studies do not clearly show MedX’s efficacy over other exercise programs.”

Although there is limited evidence that when used as a training device, the MedX system can help to increase the strength of the lumbar as well as the cervical extensors, it has not been proven that the MedX machines are more effective than standard exercise equipment in functional strengthening. Further investigation, especially controlled studies with pain patients is needed to demonstrate the accuracy of differentiation between normal subjects and patients, especially patients with non-spinal cord injuries of the cervical spine. Additionally, more research is needed to define the contribution of this equipment to patient management, especially in relation to the significant outcomes of psychological distress, changes in daily activities, and ability to return to work in such patients.

The Isostation B-200 lumbar dynamometry equipment has been suggested for use for the evaluation and rehabilitation of persons with LBP. Available evidence fails to establish the clinical effectiveness and significance of the use of the Isostation B-200 lumbar dynamometer for isometric and isokinetic muscle testing (spinal motion and trunk function) and rehabilitation in patients with LBP. More research is needed to
establish the ability of this technology to discriminate between normal subjects and patients, to establish test-retest reliability, and to define its contribution to and role in patient management. Additionally, further research is needed to evaluate the relationship between dynamometric technology, psychological tests and behavior assessments.

The Cybex back system has been proposed for use for evaluation and rehabilitation of persons with LBP. In addition, the Cybex back system has not been proven to be superior to any other particular brand of exercise equipment for administering physical therapy.

It has not been proven that the Cybex system is more effective than standard exercise equipment in functional strengthening. More research is needed to increase confidence in interpretation of abnormal range of motion and strength data, to define rehabilitation goals, and more importantly to define the contribution of this equipment to the management of persons with LBP, especially in relation to health outcomes.

Other brands of isokinetic devices used for quantification of muscle strength include the Kin-Com Isokinetic Muscle Testing Device and the Biodex Muscle Testing Device.

In a cross-sectional study, Gruther and colleagues (2009) examined the accuracy and long-term reliability of dynamometric trunk muscle strength and endurance tests in patients with chronic LBP. A total of 32 patients with chronic LBP, 19 healthy controls and 15 patients with chronic headache matched for age, sex and body mass index were included in the study. Both patient groups and healthy controls performed isokinetic and isometric trunk extensor and flexor tests on a Biodex 2000 dynamometer. The Biering-Sørensen test served to examine back muscle endurance. Borg-Category-Ratio-Scales CR-10 rated participants' body experience immediately before and after the testing. Patients with chronic LBP repeated measurements after 3 weeks.
Among dynamometric tests, isokinetic measurements revealed the best area under the curve (AUC = 0.89) for the discrimination between patients with chronic LBP and healthy controls. Reliability testing revealed highly significant learning effects for isometric trunk flexion and isokinetic measurements. The Biering-Sørensen test demonstrated excellent accuracy (AUC = 0.93) and no learning effects. Borg-category-ratio-scale ratings were not associated with the observed changes. The authors concluded that in patients with chronic LBP, dynamometric trunk muscle measures are limited to muscle function assessment purposes. Monitoring treatment outcome in these patients with these measures appears to be problematic because of learning effects. Based on these findings, the authors recommended the Biering-Sørensen test for management of chronic LBP rehabilitation.

Hand-Held Dynamometers

According to the manufacturer, the Lafayette Manual Muscle Testing (MMT) System is an ergonomic hand-held device for objectively quantifying muscle strength. The test is performed with the clinician applying force to the limb of a patient. The objective of the test is for the clinician to overcome or “break” the patient’s resistance. The MMT records the peak force and the time required to achieve the “break” providing reliable, accurate, and stable muscle strength readings that conform to most manual muscle testing protocols. The manufacturer states that the Lafayette MMT also has customizable options for data storage, preset test times, and force thresholds.

Published data on the Lafayette MMT includes small studies of its use in a research setting (Tsimaras et al, 2004; Klygile et al, 2003). There are no data on clinical outcomes with the use of the device. Other brands of hand-held dynamometers include the NIcholas Manual Muscle Tester and the Hoggan microFET.
Khan Kinetic Treatment

The Khan Kinetic Treatment (KKT), manufactured by Datrend Systems Inc (Richmond, British Columbia, Canada), is a medical device for the treatment of spine-related abnormalities causing pain. According to the manufacturer, the KKT uses high-frequency small-amplitude sinusoidal waves to vibrate the vertebrae and repeatedly activate associated neuromuscular structures, which evoke multiple mechanisms of pain relief. There is also a small unblinded randomized trial without placebo control, which found that, compared with a control group, the treatment group lowered both their self-recorded neck pain scores (p = 0.012) and pain medication dose (p = 0.048), although current functional assessment questionnaires (range of motion, overall activity, and recreation/work activities) did not detect changes (p = 0.233, 0.311, and 0.472, respectively) (Desmoulin et al, 2007). Limitations of this study included a lack of blinding and lack of placebo control. Other published literature on KKT spine treatment consists of a study of the effect of KKT treatment in an animal model (Desmoulin et al, 2010).

JTECH Tracker System

The JTECH Tracker Freedom Wireless Muscle Testing is designed for testing and documentation of strength loss due to injury or disease. However, there is a lack of evidence regarding the effectiveness of the JTECH Tracker muscle testing system.

Auricular Acupressure

In a systematic review and meta-analysis, Yang and associates (2017) examined the effects of auricular acupressure (AA) on pain and disability for patients with chronic LBP. These investigators carried out a search of RCTs in 4 English medical electronic databases and 3 Chinese databases; 2 reviewers independently retrieved
related studies, assessed the methodological quality, and extracted data with a standardized data form. Meta-analyses were performed using all time-points meta-analysis (ATM). A total of 7 trials met the inclusion criteria, of which 4 had the low risk of bias. The findings of this study showed that, for the immediate effect, AA had large, significant effects in improving pain within 12 weeks. As for the follow-up effect, the pooled estimates also showed promising effect at 4-week follow-up after 4-week intervention (standardized mean difference [SMD] = -1.13, 95% CI: -1.70 to -0.56), p < 0.001). However, for the disability level, the therapeutic effect of AA was not significant (MD = -1.99, 95% CI: -4.93 to 0.95), p = 0.18). No serious adverse effects were recorded. The authors concluded that the encouraging evidence of this study indicated that AA can be provided to patients with chronic LBP. However, they stated that there is a pressing need for further rigorously designed large-scale RCTs on the effects of AA in patients with chronic LBP.

The authors stated that this study had several drawbacks: (i) the limited number of studies for analysis, especially for ATM. Only 7 eligible RCTs were evaluated and there were only 2 or 3 RCTs included in some meta-analyses; thus interpreting and generalizing the findings should be cautious, (ii) the original evidence was not powerful on the whole considering the small sample sizes; and, to the authors’ knowledge, some study parameters of implementation (i.e., selection of acupoints, instructions of manual pressing, and duration of AA) were confirmed to be crucial influential factors for therapeutic effect that can impact the overall quality of the RCTs. In the future, these investigators hope systematic review can be updated based on more rigorous and powerful evidence, and (iii) the use of different interventions (e.g., Tai Chi exercise, walking training, and placebo) in controls may prevent these researchers from drawing firm conclusions about the effectiveness of AA. Moreover, only published studies were...
included in this study, leaving the unpublished negative results out of consideration may lead to the less powerful results.

Cupping Therapy

In a meta-analysis, Wang and colleagues (2017) evaluated the safety and effectiveness of cupping therapy for the patients with LBP. PubMed, Cochrane Library databases, and Embase database were electronically researched; RCTs reporting the cupping for the patients with LBP were included. The meta-analysis was conducted using Review Manager software (version 5.3, Nordic Cochrane Centre). The primary outcome was VAS scores; the secondary outcomes included ODI scores, McGill Present Pain Intensity (MPPI) scores and complications. A total of 6 RCTs were included in this synthesized analysis. The results showed that cupping therapy was superior to the control management with respect to VAS scores (SMD: -0.73, [95 % CI: -1.42 to -0.04]; p = 0.04), and ODI scores (SMD: -3.64, [95 % CI: -5.85 to -1.42]; p = 0.001). There was no statistical significant difference as regard to MPPI scores. No serious adverse event (AE) was reported in the included studies. The authors concluded that cupping therapy could significantly decrease the VAS scores and ODI scores for patients with LBP compared to the control management. Moreover, they stated that high heterogeneity and risk of bias existing in studies limited the authenticity of the findings.

Gabapentinoids

In a systematic review and meta-analysis, Shanthanna and colleagues (2017) evaluated the safety and effectiveness of gabapentinoids in adult chronic LBP (CLBP) patients. Electronic databases of Medline, Embase, and Cochrane were searched from their inception until December 20, 2016. These researchers included RCTs reporting the use of gabapentinoids for the treatment of CLBP of greater than 3 months duration, in adult patients. Study selection and data
extraction was performed independently by paired reviewers. Outcomes were guided by Initiative on Methods, Measurement and Pain Assessment in Clinical Trials guidelines, with pain relief and safety as the primary outcomes. Meta-analyses were performed for outcomes reported in 3 or more studies. Outcomes were reported as mean differences (MDs) or RRs with their corresponding 95% CIs, and I2 in percentage representing the percentage variability in effect estimates that could be explained by heterogeneity. GRADE (Grading of Recommendations Assessment, Development, and Evaluation) was used to assess the quality of evidence. Out of 1,385 citations, 8 studies were included. Based on the interventions and comparators, studies were analyzed in 3 different groups. Gabapentin (GB) compared with placebo (3 studies, n = 185) showed minimal improvement of pain (MD = 0.22 units, 95% CI: -0.5 to 0.07, I2 = 0%; GRADE: very low); 3 studies compared pregabalin (PG) with other types of analgesic medication (n = 332) and showed greater improvement in the other analgesic group (MD = 0.42 units, 95% CI: 0.20 to 0.64, I2 = 0; GRADE: very low). Studies using PG as an adjuvant (n = 423) were not pooled due to heterogeneity, but the largest of them showed no benefit of adding PG to tapentadol. There were no deaths or hospitalizations reported. Compared with placebo, the following AEs were more commonly reported with GB: dizziness (RR = 1.99, 95% CI: 1.17 to 3.37, I2 = 49); fatigue (RR = 1.85, 95% CI: 1.12 to 3.05, I2 = 0); difficulties with mentation (RR = 3.34, 95% CI: 1.54 to 7.25, I2 = 0); and visual disturbances (RR = 5.72, 95% CI: 1.94 to 16.91, I2 = 0). The number needed to harm with 95% CI for dizziness, fatigue, difficulties with mentation, and visual disturbances were 7 (4 to 30), 8 (4 to 44), 6 (4 to 15), and 6 (4 to 13) respectively. The GRADE evidence quality was noted to be very low for dizziness and fatigue, low for difficulties with mentation, and moderate for visual disturbances. Functional and emotional improvements were reported by few studies and showed no significant improvements. The authors concluded that existing evidence on the use of gabapentinoids
in CLBP is limited and demonstrated significant risk of adverse effects without any demonstrated benefit. They stated that given the lack of effectiveness, risks, and costs associated, the use of gabapentinoids for CLBP merits caution. Moreover, they stated that there is need for large high-quality clinical trials to more definitively inform this issue.

Fibromyalgia (FM) includes symptoms of widespread musculoskeletal pain. Furthermore, FM may complicate regional pain disorders such as chronic low back pain. The American College of Rheumatology (ACR) guideline-approved fibromyalgia medications include gabapentinoids, such as pregabalin and gabapentin (Goldenberg, 2017).

Decompression Belt

Cannon and colleagues (2016) evaluated the ability of a pneumatic decompression belt to restore spinal height lost following an acute bout of exercise that induced compression. This study implemented a test-retest repeated measures design in which 12 participants (2 women and 10 men) aged 21.5 ± 1.0 years; height, 179.0 ± 7.70 cm; weight, 84.0 ± 11.5 kg; were recruited from a university population and acted as their own control. All participants were healthy with no previous history of disabling back pain, and were frequent weight-trainers. A stadiometer was used to measure spinal height at baseline, then following an acute bout of exercise and then again following the intervention (use of a pneumatic decompression belt for 20 mins) or control (lying supine for 20 mins). A 2-way repeated measures ANOVA was performed on the change in spinal height in order to evaluate differences between measurement phases and intervention conditions. The use of the decompression belt increased spinal height gain (4.3 ± 3.0 mm) significantly more than the control condition (1.8 ± 1.2 mm) following an acute bout of weight-lifting exercises known to elicit high compressive loads on the lumbar spine. The authors concluded that the pneumatic decompression belt restored spinal height faster than a non-
belt wearing condition in young healthy asymptomatic participants. This was a small study (n = 12); and it did not include patients with back pain.

Furthermore, an UpToDate review on "Subacute and chronic low back pain: Nonpharmacologic and pharmacologic treatment" (Chou, 2018) does not mention decompression or pneumatic belts as a therapeutic option.

### CPT Codes / HCPCS Codes / ICD-10 Codes

Information in the [brackets] below has been added for clarification purposes. Codes requiring a 7th character are represented by "+":

<table>
<thead>
<tr>
<th>Code</th>
<th>Code Description</th>
</tr>
</thead>
<tbody>
<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>
<tr>
<td>97140</td>
<td>Manual therapy techniques (e.g., mobilization/manipulation, manual lymphatic drainage, manual traction), one or more regions, each 15 minutes</td>
</tr>
<tr>
<td>97530</td>
<td>Therapeutic activities, direct (one-on-one) patient contact (use of dynamic activities to improve functional performance), each 15 minutes [not covered for Khan Kinetic Treatment]</td>
</tr>
</tbody>
</table>

CPT codes not covered for indications listed in the CPB:

Hand held dynamometer, auricular acupressure, cupping therapy - no specific code:
<table>
<thead>
<tr>
<th>Code</th>
<th>Code Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>95831</td>
<td>Muscle testing, manual (separate procedure) with report; extremity (excluding hand) or trunk [Lafayette manual muscle testing]</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>97545</td>
<td>Work hardening/conditioning; initial 2 hours</td>
</tr>
<tr>
<td>+97546</td>
<td>each additional hour (List separately in addition to code for primary procedure)</td>
</tr>
<tr>
<td>97750</td>
<td>Physical performance test or measurement (e.g., musculoskeletal, functional capacity), with written report, each 15 minutes</td>
</tr>
</tbody>
</table>

HCPCS codes covered if selection criteria are met:

- S9117 Back school, per visit

HCPCS codes not covered for indications listed in the CPB:

- Gabapentinoids (e.g., gabapentin and pregabalin), Dr. Ho’s 2-in-1 Decompression Belt - no specific code:

ICD-10 codes covered if selection criteria are met:

- M54.00 - M54.9 Back pain

The above policy is based on the following references:

**Quantitative Muscle Testing Devices**


Orthotrac Pneumatic Vest


Back Schools


3. Raspe H, Kohlmann T, Luhmann D. The evaluation of back school programmes as medical technology - systematic review. Koln, Germany: German Agency for Health Technology Assessment at the German Institute for Medical Documentation and Information; 1997.


Khan Kinetic Treatment


Hand-Held Dynamometers


Auricular Acupressure

Cupping Therapy


Gabapentinoids

2. Goldenberg DL. Treatment of fibromyalgia in adults not responsive to initial therapies. UpToDate [online serial]. Waltham, MA: UpToDate; reviewed August 2017.

Decompression Belt

AETNA BETTER HEALTH® OF PENNSYLVANIA

Amendment to
Aetna Clinical Policy Bulletin Number: 0232 Back Pain - Non Invasive Treatments

There are no amendments for Medicaid.