



CIGNA HEALTHCARE COVERAGE POSITION

Subject Mechanical Devices for the Treatment of Back Pain

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INSTRUCTIONS FOR USE

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Coverage Position

Exercise equipment is specifically excluded under most CIGNA HealthCare benefit plans.

CIGNA HealthCare does not cover the use of ANY of the following mechanical devices for the treatment of back pain in any setting (e.g., home, office, rehabilitation, clinic) because they are considered experimental, investigational or unproven (this list may not be all-inclusive):

- quantitative muscle testing and treatment devices (e.g., MedX, Isostation B-200, Cybex, Kin-Com, and Biodex)
- vertebral axial decompression therapy devices (e.g., VAX-D, DRX, DRX2000, DRX3000, DRX5000, DRX 9000, DRS, Accu-SPINA™ System, IDD Therapy® [Intervertebral Differential Dynamics Therapy], Tru Tac 401, Lordex Power Traction device, Spinerx LDM)
- patient-operated spinal unloading devices (e.g., LTX 3000™, Orthotrac™ Pneumatic Vest)

General Background

Low back pain affects approximately 90% of the U.S. population at some point in their lives and ranks high among the reasons for physician office visits. It has been reported as the most frequent cause of disability in persons under age 45. In a majority of cases, low back pain is self-limiting and resolves with

little or no intervention, with 95% of cases resolving within 12 weeks (Kinkade, 2007; Bigos, et al., ACHR guidelines, 1994). Approximately 1.2% of individuals remain disabled at the end of one year. Recurrence or chronicity is estimated to occur in 39–79% of individuals.

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. Common causes of back pain are muscle strains and spasms, sciatica, and herniated intervertebral discs. Other less frequent but more serious causes of back pain include: malignancy, infections, fibromyalgia, osteoarthritis, osteoporosis, fractures, pelvic or abdominal disease, aortic aneurysm, and the cauda equina syndrome. Symptoms may include numbness and weakness of the lower extremities in addition to back pain. 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 (Hayes, 2001; Maher, 2004). 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.

U.S. Food and Drug Administration (FDA)

Classification of devices by the FDA proposed for the treatment of back pain varies. Some have received approval through the FDA as isokinetic testing and evaluation systems (e.g., Isostation, Cybex Systems, KinCom, Biodex Systems) and others as powered/mechanical traction devices (e.g., VAX-D, DRS, AccuSpina System). An isokinetic testing and evaluation system is a rehabilitative exercise device intended for medical purposes, such as to measure, evaluate, and increase the strength of muscles and the range of motion of joints. Powered traction devices consist of powered devices intended for medical purposes for use in conjunction with traction accessories, such as belts and harnesses, to exert therapeutic pulling forces on the person's body. These devices are regulated by the FDA as Class II devices.

The MEDX Lumbar Extension machine received approval from the FDA as an exerciser, measuring (i.e., exercise measuring equipment) and is also regulated as a Class II device.

Both the LTX 3000 and the Orthotrac Pneumatic Vest are considered Class I devices, further classified as nonpowered traction apparatus, and are subject to the lowest level of regulatory control by the FDA. These types of devices present minimal potential harm to the user and are simple in design.

Quantitative Muscle Testing Devices

Quantitative muscle testing devices have been used to quantify muscle strength and an individual's response to rehabilitation and therapy. Manual muscle testing is most commonly performed and is used to identify differences in strength between muscles, using qualitative grading to describe the strength of muscles. Newer computerized technologies have been proposed to quantify muscle strength, and some authors have reported that quantifying muscle activity and strength may prove useful in the diagnosis and management of individuals with low back pain. The MedX extension machine (MEDX Corp, Ocala, FL) and Isostation B200 (Isotechnologies, Inc., Hillsborough, NC) are two devices that have been designed for muscle testing, and to improve spinal muscle strength through pelvic stabilization and isolation of specific groups of lumbar muscles. However, evidence in the peer-reviewed scientific literature does not show that use of these devices for muscle testing is more effective than manual muscle testing.

MedX: 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 (72 degrees) or 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.

Isostation B-200: The Isostation B-200 lumbar dynamometer is a device that can measure position, torque and velocity. It allows measurement of increasing fatigue by measuring the reduction speed in performance and noting increasing motion as muscle substitution becomes necessary. The device has been recommended for use in the treatment of persons with low back pain.

Other Testing Devices: Other types of quantitative muscle testing and strengthening devices, referred to as isokinetic testing devices, measure muscle strength by applying a constant resistance over a range of motion and speed. Based on testing results, strengthening exercises may be recommended. Isokinetic exercise is exercise performed using a specialized apparatus that controls the speed of contraction within the range of motion. The exercise device provides variable resistance to movement, but allows movement at a constant speed. The device registers the force applied to it by the user, and offers the same amount of force as resistance. Cybex, Kin-Com, and Biodex are machines that provide isokinetic testing and muscle strengthening exercise. Evidence in the published scientific literature was not found demonstrating the utility of these specific devices for muscle testing or strengthening therapy.

Literature Review: There is limited evidence in the published peer-reviewed scientific literature evaluating the use of quantitative muscle testing devices. These devices have not been shown to be equally effective as other standard exercise equipment utilized in rehabilitation programs, nor is there sufficient evidence to suggest that use of quantitative muscle testing devices improves clinical health outcomes when compared to standard manual muscle testing.

A randomized controlled trial was conducted by Choi et al. (2005) to assess the effects of a lumbar extension muscle strengthening program used on individuals who underwent lumbar microdiscectomy or percutaneous endoscopic discectomy. A total of 75 individuals were randomized into a control group (n=40) or an exercise group (n=35). Six weeks after surgery, the exercise group underwent a 12-week lumbar extension exercise program using the MedX lumbar extension machine. All individuals completed the visual analog scale and Oswestry disability index to evaluate pain and disability. Return to work data was also evaluated. The authors noted significant improvements in the exercise group versus the control group when assessing lumbar extensor power (51.67% versus 17.55%, respectively; $p < 0.05$), the cross-sectional area of multifidus and longissimus muscle (29.23% versus 7.2%, respectively; $p < 0.05$), and the visual analog scale score (2.51 versus 4.30, respectively; $p < 0.05$). The number of people who returned to work four months after surgery was also higher in the exercise group, although not statistically significant ($p > 0.05$). Additionally, the Oswestry disability index scores were better in the exercise group compared to the control group (24.6 versus 30.6, respectively). The difference in pain status between groups was comparable at the end of one year. Long-term effects of the exercise program were not evaluated.

The U.S. Preventive Services Task Force (USPSTF) published an evidence update for primary care interventions to prevent low back pain (2004) as an update to the 1996 recommendations. The group reported that there was no new randomized controlled trial-based evidence that exercise or physical activity can help strengthen low back muscles to prevent low back pain.

A technology assessment was conducted by the Washington State Department of Labor and Industries (2003) evaluating the effectiveness of MedX in strengthening lumbar extensor muscles and for treating low back pain. The authors concluded that the evidence they reviewed suggested MedX may help to increase lumbar strength, although the studies do not clearly show MedX's efficacy over other conventional exercise programs.

Vertebral Axial Decompression Therapy and Devices

Vertebral axial decompression therapy, also referred to as mechanized spinal distraction therapy, has been proposed as a nonsurgical treatment for back pain. Vertebral axial decompression is based on a

theory that decreased load bearing (i.e., unloading) at the affected site will decrease pain and promote healing. These devices utilize computer-controlled mechanical tables to apply distractive tension, or stretching, along the spinal axis. Vertebral axial decompression devices are typically used in a clinic or rehabilitation setting and include the VAX-D (VAX-D Medical Technologies LLC, Oldsmar, FL), DRS system (Professional Distribution Systems, Inc., Boca Raton, FL), DRX2000 (Axiom Worldwide, Inc., Tampa, FL) and other FDA-approved devices.

VAX-D: Manufacturers suggest that use of the VAX-D table applies distractive forces in a gradual, progressive fashion through extension of the lower end of the table. The level of tension is preset on a control panel and can be increased, allowing for various decompression phases and a rest phase. Various decompression phases allow alternating cycles of distraction and relaxation. Typically, a treatment cycle consists of 15 cycles of tension and relaxation. The person lies prone on the VAX-D table. The table is split, allowing the table to slowly extend, thus decreasing load bearing in the intervertebral discs and/or intervertebral joint spaces.

Decompression Reduction Stabilization System (DRS): The DRS System has been recommended for treatment of low back pain. This device uses a bed that is split into two cushions. The DRS has a stand-on/stand-off tilt type design. The individual can step onto a foot pad, have a pelvic and chest harness attached, after which the individual and bed are lowered to a horizontal position. Distraction tension is applied by the pelvic harness while the individual's upper body is secured to the locked upper cushion via the chest harness.

DRX2000™: It is suggested by the manufacturers that DRX2000 is designed to relieve pressure on the anatomical structures that cause lower back pain. It is intended for use in the treatment of pain and disabling low back conditions caused by disc herniation, degenerative disc disease, sciatica, and posterior facet syndrome. Each treatment session begins with a physician-prescribed treatment period and is designed to provide static, intermittent and cycling distraction forces to relieve pressures. It is a stand-on/stand-off tilt type bed split into two cushions. Distraction tensions are applied to an individual via a pelvic harness while the upper body is locked to the upper cushion via a chest harness.

Accu-Spina System™

Internal disc decompression therapy using the Accu-Spina System™ (North American Medical Corp., Atlanta, GA) is a noninvasive method of treatment proposed for chronic neck or back pain. According to the manufacturer, the device is the only device certified to administer IDD Therapy® (Intervertebral Differential Dynamics Therapy). IDD therapy is a computer-directed type of physical therapy regimen which theoretically works to create negative intradiscal pressure, retraction of herniation and to promote natural healing of the damaged area. Each treatment consists of a physician-prescribed treatment on the Spina System™ and is designed to provide static, intermittent, and cycling distraction forces to relieve pressures on structures that may be causing back pain. Individuals are fitted with pelvic and torso harnesses, placed on a platform where they are reclined to a supine position; the harnesses are connected to a table and the Intelli-Decompression™ head, which is elevated 10 to 25 degrees above the individual. The system is programmed for intervals of 60 seconds decompression followed by 30 seconds of partial relaxation. Treatment sessions generally include 20 twenty-five minute treatments provided over a six-week period.

Other FDA-approved powered traction devices include the following:

- Tru Tac 401 (Henley International)
- DRX3000, 5000, 9000
- Lordex Power Traction Equipment
- Spinerx LDM

Literature Review: The published scientific data is insufficient to validate improved clinical outcomes (e.g., reduction of back pain, improved functioning) associated with vertebral axial decompression therapy. While several technology assessments have been published, effectiveness of the various devices have not been proven when compared to standard equipment or testing.

Daniel (2007) reported that there is very limited evidence in the scientific literature to support the effectiveness of non-surgical spinal decompression therapy. One randomized controlled trial, one clinical trial, one case series and seven other papers were available in the published literature for review by the author as part of an intended systematic review. Due to the limited evidence a systematic review was not done and each study was reviewed individually. The author noted many of the reviewed studies utilized the VAX-D unit. Furthermore, the intervention has not been compared to exercise, spinal manipulation, standard medical care or other less expensive conservative treatments and many better-researched treatment options are available to clinicians.

Macario and Pergolizzi (2006) conducted a systematic review of the literature to assess the efficacy of nonsurgical spinal decompression that is achieved with motorized traction for chronic discogenic low back pain. The authors reviewed data from 10 studies between 1975 and 2003. Seven were randomized controlled trials of motorized traction using various apparatus types, including split-tabletop, plain tabletop, and friction-free couch with weights. A total of 408 individuals received placebo, and 438 individuals received motorized spinal decompression. Follow-up averaged 28 weeks. None of the studies were blinded, and only three had description of the randomization method. Due to the quality of the studies, the authors could not conduct a meta-analysis; hence, a qualitative review was performed. Six of the seven randomized trials reported no difference with motorized spinal decompression, and one study reported reduced pain but not disability. In the author's opinion, the efficacy of spinal decompression achieved with motorized traction for discogenic low back remains unproven.

In a randomized, controlled study, Sherry et al. (2001) reported on the efficacy and appropriateness of VAX-D therapy compared to transcutaneous electrical nerve stimulation (TENS) therapy as a control treatment or placebo in a group of 44 individuals with chronic low back pain of greater than three months' duration. All subjects had confirmed disc protrusion or disc herniation. The VAX-D treatment group (n=19) had treatment five times a week for four weeks, then once weekly for four weeks. The TENS treatment group (n=21) had treatment 30 minutes daily for 20 days, then once weekly for four weeks. Non-narcotic pain relievers and anti-inflammatory medication were administered in all subjects as required. The outcomes were self-reported; a successful outcome was defined as a 50% reduction in pain using the Visual Pain Analogue Scale and an improvement in the level of functioning as rated by individually selected disability ratings. The authors reported a 0% (0/21 subjects) success rate in the TENS treatment group compared to a success rate of 64.8% (13/19 subjects) in the VAX-D treatment group immediately following the treatment session ($p < 0.001$). Follow-up at six months consisted only of the successful VAX-D cases (13/19), with a reported continued success in 70% (7/10) of the studied population (two individuals were lost to follow-up, and one suffered other injury). While the authors reported a positive short-term outcome, the study was limited by small sample size, self-reported outcome measures, and lack of blinding. Four individuals were excluded from the analysis because of study withdrawal or failure to meet inclusion criteria. No data were provided regarding procedure-related complications; therefore, no conclusion could be drawn regarding the safety of VAX-D.

In review of a single study of DRS therapy (Shealy, Borgmeyer, 1997), the authors reported on a comparison of DRS therapy to conventional traction for both ruptured lumbar discs and chronic facet arthrosis. The subjects (n=39) were randomized to DRS therapy (n=25) or conventional traction treatment groups (n=14). The authors concluded that, for individuals with ruptured intervertebral discs, the results were good to excellent for 86% of persons treated with DRS, compared to good results in 55% of those treated with traction (none of this treatment group had excellent results). For the facet arthrosis group, 75% of those treated with DRS had good to excellent results, while 50% treated with traction had good to excellent results. The scale used to quantify results in this study was not clearly defined, and the study consisted of small sample size lacking clearly defined methods of randomization.

The Agency for Healthcare Research and Quality published an evidence report regarding decompression therapy for the treatment of lumbosacral pain (Jurecki-Tiller, et al., 2007). Ten published articles in total were reviewed. Upon conducting their review, the authors noted that the current evidence is too limited in quality and quantity to allow for evidence based conclusion regarding efficacy of decompression therapy when compared to other nonsurgical treatment options for back pain.

The Workers Compensation Board (WCB) of British Columbia, Evidence Based Practice Group (2005) conducted a systematic review of vertebral axial decompression for low back pain and concluded that

there is no evidence that the VAX-D system is effective in treating chronic low back pain associated with herniated disc, degenerative disc, posterior facet syndrome, sciatica or radiculopathy.

Hayes, Inc. conducted a review of the literature (2003) of mechanized spinal distraction therapy for low back pain. They suggested that, although limited data suggests therapy may reduce back pain in some individuals, the evidence is flawed and limits credibility of the study results. Their assessment of the evidence did not provide sufficient data to support the safety and efficacy of the VAX-D or DRS device. Updated searches of the literature, periodically conducted by Hayes since the initial report, have not provided any new evidence to support the safety and efficacy of these devices.

The Medical Services Advisory Committee (MSAC) of the Department of Health and Aging, Australia, conducted a technology assessment (2001) of vertebral axial decompression therapy for chronic back pain. There was insufficient evidence to support the safety and efficacy of vertebral axial decompression therapy.

A technology assessment was conducted by the Washington State Department of Labor and Industries (1999) and concluded that, while the FDA has approved the VAX-D as a form of traction, as a treatment modality it has not been established as more or less beneficial as other forms of traction.

Patient-Operated Spinal Unloading Devices

Some spinal unloading devices may be operated by the individual in a home setting. Generally, the use of spinal unloading devices is proposed as a method of treatment for persons with subacute or chronic low back pain and who have failed either standard medical or surgical therapy. Two devices currently available are the LTX 3000™ (Spinal Designs International, Minneapolis, MN) and the Orthotrac™ Pneumatic Vest (Orthofix, Inc., Huntersville, NC). The LTX 3000 employs gravitational force provided by the individual's body mass as a spinal unloading mechanism. The Orthotrac Pneumatic Vest uses pneumatic pressure to apply force in order to shift weight off the lower back onto the hips.

LTX 3000: The LTX 3000 is a gravity-dependent axial spinal unloading device that consists of an adjustable seat strap and rib support pads that are used to stabilize the upper body by engaging the lowest portion of the rib cage. After adjusting rib support pads, the individual lowers the seat strap to induce unloading of the spine. Theoretically, unloading occurs as a result of the downward force provided by body mass. Proper training in adjustment and use of the device is required for safe use in the home. The LTX 3000 is often used as part of rehabilitation programs, such as the Low Back Rehabilitation Program, the ReSpond Program, and, more recently, the LIFEBACK™ Spine Programs. These programs are proposed for those persons who have reached maximum therapeutic benefit of physical therapy or chiropractic care and whose pain limits activities of exercise and/or work. According to the manufacturer, recommended use of the device is 3–4 times a day for sessions of 10–15 minutes lasting 2–3 months.

Orthotrac Pneumatic Vest: The Orthotrac Pneumatic Vest is a custom-made device intended to be worn 2–3 times a day for 30–60 minutes each session. It is a spinal decompression orthotic device that is theoretically designed to offload and stabilize the lower back, using air pressure to provide support. It is proposed that when worn, the device applies a decompressive force to the spine, transferring the weight from the upper torso to the hips, preventing compression and aggravation of the lower back. The amount of force on the spine is controlled by the individual through a manual inflation device, with pressure prescribed to offload approximately 50% of the person's weight. The individual can deflate the device to reduce pressure at any time. It is suggested that use of the device alleviates pain and improves function and quality of life.

Literature Review: There are few published clinical trials evaluating the safety and efficacy of patient-operated spinal unloading devices compared to other well-accepted pain treatment modalities for the treatment of back pain. In a preliminary study, Dallolio (2005) reported on a case series of 41 subjects with radicular pain due to degenerative discopathy. The individuals were treated with an Orthotrac pneumatic lumbar vest for 60 minutes, three times a day, for five weeks. The authors reported, "Thirty-two subjects showed a significant subjective and clinical improvement with subsequent better quality of life." All subjects reported a decrease or a disappearance of radicular pain. The authors acknowledged the device seemed to be effective for spinal decompression; however, further multicenter and interdisciplinary studies involving larger numbers of individuals are required to confirm those results. The study was

limited by lack of controls, lack of comparative treatments, short-term outcomes, and a small study population.

Two published literature sources address the mechanical responses and safety of the LTX 3000 specifically. Podesin and Iuzzo (1998) studied lumbar unloading in 17 healthy subjects who had not experienced a significant episode of low back pain within six months, using the LTX 3000. In this case series, the authors addressed the safety of the device by measuring forces applied to the body and associated changes in physiological responses (e.g., heart rate, blood pressure, respiratory rate) during spinal unloading. The authors noted that the applied forces of spinal unloading did cause changes in physiological responses but that the changes were reversible, clinically unimportant and not contraindications to use of the device by the general population. Nonetheless, due to a small sample population and limited evaluation measures, strong conclusions regarding the safety and efficacy of the device cannot be made.

A case series conducted by Janke et al. (1997) evaluated the biomechanical effectiveness of the LTX 3000 Lumbar Rehabilitation System used on 14 healthy subjects who had not experienced a significant episode of back pain for six months. Outcome measures were the degree of lumbar lengthening and curvature reduction. Authors reported that their results indicated proper use of the LTX 3000 induced significant lumbar lengthening and curvature reduction in healthy subjects during treatment. However, this small case series did not provide data on those persons with back pain, nor did the study provide data on duration of effect on intervertebral disc spaces. Therefore, no conclusions can be drawn regarding biomechanical effect, relief of symptoms or improvement of function.

Hayes conducted a review of the literature of spinal unloading devices for the treatment of low back pain evaluating the LTX 3000 Lumbar Rehabilitation System and the Orthotrac Pneumatic Vest (Hayes, 2001). They concluded from their review that there is insufficient evidence from peer-reviewed published studies to conclude axial spinal unloading devices are effective in the management of low back pain. Hayes did not find any evidence that these devices improved clinical outcomes. They reported the data from the manufacturers indicated there was improved function and relief of pain, although the data was derived from uncontrolled and unblinded studies that have not undergone peer review. Updated searches of the literature, periodically conducted by Hayes since the initial report, have not provided any new evidence to support the safety and efficacy of these devices.

All other data reviewed were obtained from the device manufacturers. The literature lacks published clinical studies to support the safety and efficacy of spinal unloading devices for the treatment of back pain and specific patient-selection criteria have not been established. In addition, there is mixed evidence in the literature supporting the use of back braces and lumbar supports, in general, for the treatment of back pain. For example, a Cochrane systematic review concluded that there is still a need for high-quality randomized trials assessing the effectiveness of lumbar supports (van Tulder, et al., 2000).

Summary

Several noninvasive treatments for back pain, which include quantitative muscle testing and therapy, vertebral axial decompression, and patient-operated spinal unloading devices, have emerged; however, there are few well-designed controlled clinical trials available to support improved clinical outcomes when these treatments are compared to standard equipment used for rehabilitation and physical therapy. The few published studies have had methodological flaws, such as lack of blinding, self-reported outcomes, small populations, and short-term follow-up. There is insufficient evidence in the published, peer-reviewed scientific literature to demonstrate that any of these mechanical devices used for the treatment of back pain are as effective as or more effective than standard established methods of treatment.

Coding/Billing Information

Note: This list of codes may not be all-inclusive.

Experimental/Investigational/Unproven/Not Covered:

CPT* Codes	Description
95831 [†]	Muscle testing, manual (separate procedure) with report; extremity (excluding hand) or trunk
95851 [†]	Range of motion measurements and report (separate procedure); each extremity (excluding hand) or each trunk section (spine)
97012 [†]	Application of a modality to one or more areas; traction, mechanical
97039 [†]	Unlisted modality (specify type and time if constant attendance)
97750 [†]	Physical performance test or measurement (eg, musculoskeletal, functional capacity), with written report, each 15 minutes
97799 [†]	Unlisted physical medicine/rehabilitation service or procedure

HCPCS Codes	Description
E0830 [†]	Ambulatory traction device, all types, each
E0941 [†]	Gravity-assisted traction device, any type
E1399 [†]	Durable medical equipment, miscellaneous
S9090	Vertebral axial decompression, per session

ICD-9-CM Diagnosis Codes	Description
724.2	Lumbago
724.5	Unspecified backache
	Multiple/Varied

[†] **Note: Experimental, investigational, or unproven and not covered when used to report quantitative muscle testing and treatment devices, vertebral axial decompression therapy devices, or patient-operated spinal unloading devices for the treatment of back pain.**

***Current Procedural Terminology (CPT®) ©2007 American Medical Association: Chicago, IL.**

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