



A CMS Contracted Agent

National Government Services, Inc.
www.NGSMedicare.com

Medicare

Comments and Responses Regarding Draft Local Coverage Determination Chiropractic Services

As an important part of Medicare Local Coverage Determination (LCD) development, National Government Services solicits comments from the provider community and from members of the public who may be affected by or interested in our LCDs. The purpose of the advice and comment process is to gain the expertise and experience of those commenting.

We would like to thank those who suggested changes to the draft Chiropractic Services LCD. The official notice period for the final LCD begins on October 1, 2008, and the final determination will become effective on November 15, 2008.

Comment: A number of individuals wrote asking that the policy not be put in place due to their concerns about the “subluxation theory” of chiropractic care, the inability to detect a subluxation on physical examination, and whether there was evidence to support the efficacy of chiropractic spinal manipulation. Cited references were requested.

Response: References^{i,ii,iii,iv} received were reviewed and additional papers secured and read. Brantington¹ reviewed the concept of subluxation, especially in relation to chiropractic care. He concluded, “The word “subluxation” should be abandoned as a term denoting the manipulable joint lesion.” However, in his reply to comments,^v he reiterated his desire to stimulate scientific inquiry but also noted his agreement that spinal manipulative therapy could be beneficial. It was noted that his initial reference is often quoted, but his response to comments is not.

The AHCPR monograph³ was prepared to provide “a comprehensive and balanced overview of the chiropractic profession and its current and future potential role in the United States health care system.” History of the profession, belief system, training, licensure and scope of practice, practice content, research, biological rationale for possible benefits of spinal manipulation, benefits and risks of spinal manipulation were among the topics included.

Leboeuf-Yde’s⁴ commentary outlined the five basic chiropractic tenets regarding subluxation. She challenged her colleagues to review the lack of supporting scientific evidence.

The term “subluxation” is used in 42 CFR 410.21 (b) (1) which states, “Medicare Part B pays only for a chiropractor’s manual manipulation of the spine to correct a subluxation if the subluxation has resulted in a neuromusculoskeletal condition for which manual manipulation is appropriate treatment.” In addition, the CMS manuals also liberally use the term, “subluxation.” Thus, the local coverage determination will also use the term and address medical necessity as defined in the CMS manuals.

Comment: It was requested the following paragraph be removed because it would potentially restrict beneficiary access to care.

An acute exacerbation of a chronic subluxation must represent an acute change that is a marked deterioration of the patient's condition and is causing significant interference with activities of daily living. "Active treatment" may only occur as long as the patient is achieving significant clinical improvement.

Response: The paragraph had been developed because chiropractors often asked for clarification of an acute exacerbation of a chronic subluxation in relation to medical necessity of care. The paragraph was modified as follows.

An acute exacerbation is a temporary but marked deterioration of the patient's condition that is causing significant interference with activities of daily living due to an acute flare-up of the previously treated condition. The patient's clinical record must specify the date of occurrence, nature of the onset, or other pertinent factors that would support the medical necessity of treatment. As with an acute injury, treatment should result in improvement or arrest of the deterioration within a reasonable period of time.

Comment: We were asked to clarify the definition of the five extraspinal regions for the ribs.

Response: The language from the *CPT Assistant* was used so that it reads, ".....rib care (excluding costotransverse and costovertebral joints)...."

Comment: Under "Initial Documentation Requirements," the initial statement is "History as above." However, the information is missing.

Response: The information will be added.

Comment: "Documentation Requirements: Subsequent Visits" included the statement, "Documentation of the presence or absence of a subluxation must be present at every visit." There was concern that this statement was not in the CMS manual, and that the chiropractic physician might think that an x-ray was required.

Response: The "Documentation: P.A.R.T. Evaluation Process" clearly describes the method to document a subluxation by physical examination. The "Limitations" portion of the policy and other information in "Documentation Requirements" state, "The precise level(s) of the subluxation must be specified to substantiate a claim for manipulation of each spinal region(s)." Therefore, "Documentation of the presence or absence of a subluxation" will remain.

Comment: "Documentation: X-ray/CT/MRI" included a requirement that a written report, including interpretation and diagnosis by a physician must be present in the patient's medical record. There was concern this did not recognize the ability of a chiropractic physician to interpret radiographs and that there might be instances in which the report could not be obtained.

Response: A statement will be added that any inability to obtain the report must be documented. The draft policy already contains a statement requiring the chiropractor's review of the x-ray (CT/MRI).

Comment: Secondary “ICD Codes that Support Medical Necessity” in the current Indiana and Kentucky LCDs are organized into three groups, two of which are designated as “Moderate-Term Treatment” and “Long-Term Treatment.” Similar groupings were requested for the final version of the draft LCD.

Response: The necessary length of treatment for the same diagnosis will vary from patient to patient. Therefore, the diagnoses will not be listed by anticipated duration of treatment.

Comment: Several ICD-9-CM diagnosis codes that are currently on the policies are not present on the draft. No diagnoses for tension, migraine, or simply “headache” are present.

Response: Diagnoses for tension and migraine headaches were not included due to concern that the medical literature did not support the efficacy of chiropractic spinal manipulation. Cervicogenic headache, although a somewhat controversial entity, does not have a specific ICD-9-CM diagnosis code. Headaches due to musculoskeletal disorders of the cervical spine, termed cervicogenic headaches may have been diagnosed as tension headaches in some patients. The International Headache Society (HIS) has developed criteria for cervicogenic headache. Syaastad’s criteria published in 1998 are also frequently used.^{vi}

Literature was obtained and reviewed. One commenter provided abstracts from the literature. Bronfort et al. reviewed nine randomized clinical trials of spinal manipulative therapy (SMT) for chronic headaches^{vii}. Methodological quality scores ranged from 21 to 87 using a 100 point scale. The authors concluded SMT appeared to have a better effect than massage for cervicogenic headache, although the trial was considered unusual in that it was conducted in two stages. SMT was also felt to have an effect comparable to amitriptyline for migraine and tension headaches. However, it was noted that withdrawal of the amitriptyline at the end of treatment was inconsistent with normal clinical practice. They also stated that longer periods of observation after treatment were necessary to determine the value of using SMT for tension headaches. The statistical and subsequent analyses of two other trials for migraine headache were considered uncertain. The addition of SMT to soft tissue massage did not improve outcomes for episodic tension-type headache in another study. Further testing in well-designed trials was recommended prior to making firm conclusions.

Astin and Ernst^{viii} also published a review of eight randomized clinical trials using SMT for headache. There was one study not included in the review summarized immediately above which employed SMT or detuned interferential therapy (electrodes placed on the patient but no current used). Although the latter study reported fewer headaches and less medication use than the controls, the review authors noted there were considerable methodological and statistical problems that called the validity of the findings into question. It was concluded that despite claims of SMT efficacy for treatment of headaches, the current data do not support such definitive conclusions.

Cervicogenic headache, since it is considered due to musculoskeletal disorders of the cervical spine, would theoretically be more amenable to SMT. However, the data are less than robust. Referenced studies include Nilsson et al.^{ix} and Jull et al.^x Nilsson’s study randomized patients to SME or low-level laser in the upper cervical region accompanied by deep friction massage in the lower cervical/upper thoracic region. Headache hours per day and analgesic use decreased in the patients receiving SMT. The study was conducted in two stages; the initial trial showed the SMT patients had a better outcome but the results were not statistically significant thought to be due to the number of subjects.

Jull’s study had 200 participants who were randomized into four groups: SMT, exercise therapy, combined SMT and exercise therapy, and a control group. Both SMT and exercise therapy significantly reduced headache

frequency and intensity and the decreased neck pain and beneficial effects were maintained. The combined therapies did not show a statistically significant advantage over the individual treatments.

All of the studies regarding migraine and tension headache are aimed at prophylactic treatment. Services that “seek to prevent disease, promote health and prolong and enhance the quality of life, or maintain or prevent deterioration of a chronic condition” are considered as maintenance therapy by Medicare. Maintenance chiropractic therapy is not covered by Medicare. In addition, it is felt the literature does not adequately support the efficacy of SMT for these conditions.

Chiropractic manipulative therapy to treat the cervical abnormality responsible for acute episodes of cervicogenic headaches meeting IHS or Syaastad’s criteria will be allowed. Maintenance therapy for cervicogenic headaches will not be allowed.

Comment: There were diagnosis codes on current policies that were omitted on the draft LCD. Lists of requested diagnoses were provided but not medical literature to support the efficacy of chiropractic treatment.

Response: Requested diagnoses of a spinal condition were added, unless a more specific diagnosis was present (e.g., Post-laminectomy syndrome, unspecified region). Please see the following list (Y = yes; N = no).

ICD-9-CM	Description	Added
333.83	Spastic torticollis	N
353.0	Brachial plexus lesions	N
353.1	Lumbosacral plexus lesions	N
355.2	Mononeuritis of lower limb; other lesion of femoral nerve	N
355.8	Mononeuritis of lower limb; unspecified	N
719.48	Pain in joint; other specified sites	N
721.6	Ankylosing vertebral hyperostosis	Y
721.7	Traumatic spondylopathy	N
721.9	Spondylosis of unspecified site (fifth digit required)	N
722.80	Postlaminectomy syndrome of unspecified region	N
723.0	Spinal stenosis of cervical region	Y
723.2*	Cervicocranial syndrome	N
723.3**	Cervicobrachial syndrome (diffuse)	N
723.5	Torticollis, unspecified	Y
723.8	Other syndromes affecting cervical region	Y
724.01	Spinal stenosis of thoracic region	Y
724.02	Spinal stenosis of lumbar region	Y
728.85	Spasm of muscle	N
729.1	Myalgia and myositis, unspecified	N
729.4	Fasciitis, unspecified	N
729.5	Pain in limb	N
737.0	Adolescent postural kyphosis	Y
737.12	Kyphosis postlaminectomy	Y
737.19	Other kyphosis, acquired	Y
737.20	Lordosis (acquired) (postural)	Y
737.21	Lordosis postlaminectomy	Y

737.29	Other lordosis acquired	Y
737.30	Scoliosis (and kyphoscoliosis) idiopathic	Y
737.34	Thoracogenic scoliosis	Y
737.40	Unspecified curvature of spine associated with other conditions	Y
737.41	Kyphosis associated with other conditions	Y
737.42	Lordosis associated with other conditions	Y
737.43	Scoliosis associated with other conditions	Y
738.4	Acquired spondylolisthesis	Y
738.5	Other acquired deformity of back or spine	Y
754.2	Congenital musculoskeletal deformities of spine	Y
756.10	Congenital anomaly of spine unspecified	Y
756.11	Congenital spondylolysis of lumbosacral region	Y
756.12	Spondylolisthesis congenital	Y
781.92	Abnormal posture	N
907.3	Late effect of injury to nerve root(s), spinal plexuses(es) and other nerves of trunk	Y
953.0	Injury to cervical nerve root	Y
953.1	Injury to dorsal nerve root	Y
953.3	Injury to sacral nerve root	Y
953.4	Injury to brachial plexus	N
953.5	Injury to lumbosacral plexus	N
954.0	Injury to cervical sympathetic nerve excluding shoulder and pelvic girdles	N
954.8	Injury to other specified nerve(s) of trunk excluding shoulder and pelvic girdles	N
956.0	Injury to sciatic nerve	N
956.1	Injury to femoral nerve	N
956.2	Injury to posterior tibial nerve	N
956.3	Injury to peroneal nerve	N
956.4	Injury to cutaneous sensory nerve lower limb	N
956.5	Injury to other specified nerve(s) of pelvic girdle and lower limb	N

* Cervicocranial syndrome or Barre'-Lie'ou syndrome is not an agreed upon neurological entity.

**Cervicobrachial syndrome (diffuse) is defined in the ICD-9-CM manual as "Complex of symptoms due to scalenus anterior muscle compressing the brachial plexus; pain radiates from shoulder to arm or back of neck."

ⁱ Brantingham JW. A critical look at the subluxation hypothesis. *J Manipulative Physiol Ther* 1988;11:130-132.

ⁱⁱ Tullberg T, Blomberg S, Branth B et al. Manipulation does not alter the position of the sacroiliac joint: a roentgen stereophotogrammetric analysis. *Spine* 1998;23(10):1124-1128.

ⁱⁱⁱ Cherkin DC, Mootz RD (editors). *Chiropractic in the United States: Training, Practice, and Research*. AHCPR Publication No. 98-N002. Agency for Health Care Policy and Research. Public Health Service, U.S. Department of Health and Human Services, December 1997.

^{iv} Leboeuf-Yde C. How real is the subluxation? A research perspective. *J Manipulative Physio Ther* 1998;21:492-494

^v Brantingham JW. A critical look at the subluxation hypothesis – In reply. *J Manipulative Physiol Ther* 1989;12:154-155.

^{vi} Syaastad O., Fredriksen A, Pfaffenrath V. Cervicogenic headache: diagnostic criteria. *Headache* 1998;38:442-445.

^{vii} Bronfort G, Assendelft JJ, Evans R, Haas M, Bouter L. Efficacy of spinal manipulation for chronic headache: a systematic review. *J Manipulative Physio Ther* 2001;24(7):457-466.

^{viii} Astin JA, Ernest #. The effectiveness of spinal manipulation for the treatment of headache disorders: a systematic review of randomized clinical trials. *Cephalgia* 2002;22:617-623.

^{ix} Nillson N, Christensen HW. The effects of spinal manipulation in the treatment of cervicogenic headache. *J Manipulative Physiol Ther* 1997;20:326-330.

^x Jull G, Trott P, Potter H, Zito G, Niere K, Shirley D, Emberson J, Marschner I, Richardson C. A randomized controlled trial of exercise and manipulative therapy for cervicogenic headache. *Spine* 2002;27(17):1835-1843.