Clinical Pr	actice Guideline:	Spinal Manipulation for Treatment of Neck Pain
Date of Im	plementation:	September 18, 2008
Product:		Specialty
POLICY American S	specialty Health - Spe	cialty (ASH) clinical committees have determined that
spinal mani been establ benefit:risk	pulation for treatment of special pulation for treatment of ished in the scientific profile.	of non-acute neck pain is professionally recognized, has literature as clinically effective, and has a favorable
ASH clinica	al committees have det	ermined that spinal manipulation for treatment of acute
neck pain	is clinically effective	e, may have a favorable benefit:risk profile and is
professiona	lly recognized. The ev	vidence supporting spinal manipulation for acute neck
pain is preli	minary and not conclu	sive, a trial period of spinal manipulation for acute neck
pain to asse	ss effectiveness for ind	lividual patients is supported by the available evidence.
PROCESS	AND DEFINITIONS	1
When devel	oping reviewing and	approving clinical policy. ASH peer-review committees
consider wh	the technique/pro	ocedure:
• Is e	stablished as clinically	effective by:
	 Scientific informat 	tion published in an acceptable peer-reviewed clinical
	science resource, a	nd
	• The consensus opin	nion of the Evidence Evaluation Committee (EEC) when
	available;	
• Is p	rofessionally recognize	ed by:
	• Inclusion in the e	ducational standards accepted by the majority of the
	professions' educa	tional institutions,
	• Wide acceptance a	nd use of the practice, and
	• Recommendations	for use made by healthcare practitioners practicing in
D	the relevant clinica	i area;
• Pos	es a health and safety f	isk; and
• Is p	lausible or implausible	, mash an ions of health and disease that can be availained
	• A dener, theory, of	framework of scientific methods reasoning and
	available knowledge	be is considered plausible
	\circ A treatment interve	ention or diagnostic procedure that requires the existence
	of forces. mechani	sms, or biological processes that are not known to exist
	within the curren	t framework of scientific methods, reasoning, and
	available knowledg	ge is considered implausible.

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1	
2	Substitution harm (indirect harm): Compromised clinical outcomes caused by:
3	• Utilizing a specific diagnostic or therapeutic procedure when the safety, clinical
4	effectiveness, or diagnostic utility is either unknown or is known to be unsafe,
5	ineffective, or of no diagnostic utility, instead of a diagnostic or therapeutic
6	procedure known to be safe, be clinically effective, or to have diagnostic utility; or
7	• The utilization of a diagnostic or therapeutic procedure that is substantially less
8	effective or safe than another procedure with established safety, and clinical
9	effectiveness or utility.
10	
11	Labeling effects (non-specific harm): The harm that results from identifying in a patient
12	a condition or a finding that is not clinically valid.
13	
14	Safe: The terms "safe" and "safety," are used only with specific reference to the absence
15	of direct harm. Direct harm would include any injury to a patient caused by the
16	mechanical, thermal, biological, chemical, pharmacological, electrical,
17	electromagnetic, or psycho-dynamic properties of a diagnostic or therapeutic
18	procedure, and as such, the procedure would be considered unsafe.
19	Direct horms Any injury to a notion toological by the machanical thermal hielogical
20	chamical pharmacological electrical electromagnetic or psycho dynamic
21	properties of a diagnostic or therapeutic procedure
22	properties of a diagnostic of incrapeutic procedure.
23	Benefit versus risk profile: The relative effectiveness or utility of a therapeutic
25	intervention or diagnostic procedure versus its potential for direct harm.
26	 Positive (benefits outweigh risks).
27	• Negative (risks outweigh benefits), or
28	 Equivocal (available information is inconclusive).
29	
30	Description/Background
31	Spinal manipulation is practiced by a variety of health care providers including, but not
32	limited to: chiropractors, osteopaths, physical therapists, and naturopaths. Health care
33	practitioners may differ with respect to the specific spinal manipulation techniques they
34	use, reflecting the diversities in their education, training, and philosophical foundations.
35	Manipulative therapy uses a number of techniques that can be classified as either
36	manipulations or mobilizations. Mobilization techniques include grades I-IV, as well as
37	grade V manipulation which is similar to the HVLA thrust manipulations (Peterson &
38	Bergmann, 2002). The primary objectives of spinal manipulation in the treatment of spine
39	pain are to alleviate musculoskeletal pain, muscle spasm, and functional impairment of the
40	spine. This form of manipulation is a therapeutic procedure characterized by controlled
41	torce, leverage, direction, amplitude, and velocity (directional, high velocity, low

42 amplitude thrust) (Peterson & Bergmann, 2002).

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1 Evidence and Research

In two early meta-analyses, Aker, et al. (1996) concluded that there was preliminary 2 evidence for the effectiveness of combination therapy that included spinal manipulation, 3 and Hurwitz, et al. (1996) suggested some benefit of manipulation over usual care for sub-4 acute and chronic patients in the short term. Kjellman, et al. (1999) found two (2) high 5 quality studies that were slightly positive, but the evidence was insufficient to make a 6 general conclusion. In a review of reviews, Hoving, et al. (2001) found a dearth of evidence 7 from primary studies on neck pain. They warned that reviews in general require careful 8 consideration because of the disparity in methodology, information, and conclusions. 9 10

Gross, et al. (2004a; 2004b; 2007) published a Cochrane review in 2004; the review was updated in 2007. The meta-analysis showed that manipulation and/or mobilization was no better than placebo, no treatment, or other therapies. However, a combination of manipulation, mobilization, and exercise therapies had a positive effect on chronic mechanical neck pain.

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Bronfort, et al. (2004) conducted a best evidence synthesis (qualitative systematic review). 17 There was preliminary but inconclusive support of manipulation for acute neck pain from 18 one lower quality trial. The evidence for a mix of acute and chronic patients was unclear. 19 There was high quality evidence supporting manipulation for chronic neck pain. 20 Manipulation was superior to general practice in the short term and similar to high tech 21 rehabilitative exercise in the short and long term. The authors concluded that manipulation 22 is a viable option for the treatment of neck pain. They also suggested that future trials 23 should address well defined subgroups and optimal quantity of care. 24

25

Conlin, et al. (2005) found three (3) observational studies in support of spinal manipulation,
but noted no randomized trials. Vernon, et al. (2005; 2007) conducted two systematic
reviews. They found moderate- to high-quality evidence that manipulation produces
clinically important improvement in the short and long term for neck pain patients without
headaches or whiplash.

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Hurwitz, et al. (2008) conducted a best evidence synthesis for the Bone and Joint Decade 32 2000 - 2010 Task Force on Neck Pain and Its Associated Disorders. They found 33 manipulation likely to be helpful for neck pain without acute whiplash-associated 34 disorders. They concluded, "Our best evidence synthesis suggests that therapies involving 35 manual therapy and exercise are more effective than alternative strategies for patients with 36 neck pain" (Hurwitz, et al., 2008). The American Physical Therapy Association's (APTA) 37 guidelines on neck pain recommend cervical mobilization/manipulation with exercise for 38 treatment of neck pain. They also recommend thoracic spine manipulation for reducing 39

pain and disability in patients with neck and neck-related arm pain; however the evidence
was considered weak by the APTA (Childs et al., 2008).

3

Bronfort et al. (2010) authored a concise summary of the scientific evidence for manual 4 therapies for the management of a variety of conditions, including neck pain. They reported 5 that moderate quality evidence exists for mobilization combined with exercise for 6 treatment of acute whiplash disorders and spinal manipulation/mobilization with exercise 7 for chronic non-specific neck pain. Inconclusive evidence was found for spinal 8 manipulation as a single treatment for neck pain. Clar et al. (2014) in an updated systematic 9 review and extension of the Bronfort et al. (2010) "UK evidence report" noted that 10 evidence continued to be inconclusive but favorable for spinal manipulation/mobilization 11 alone for neck pain. Several studies have supported thoracic spinal manipulation as 12 effective for acute/subacute neck pain (González-Iglesias et al., 2009; Bronfort et al., 2010; 13 Cross et al., 2011; Puenttedura et al., 2011; Lau et al., 2011; Massaracchio et al., 2013; 14 Huisman et al., 2013; Casanova-Méndez et al., 2014). 15

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Bronfort et al. (2012) completed a randomized trial on spinal manipulation, medication and 17 home exercise with advice for acute and subacute neck pain. They concluded that spinal 18 manipulation was more effective than medication in the short and long term for acute and 19 subacute neck pain; however home exercise and advice resulted in similar outcomes. Evans 20 21 et al. (2012) evaluated supervised exercise with and without spinal manipulation in a RCT design for treatment of chronic neck pain. Three groups were compared: high dose 22 supervised exercise with manipulation; high dose supervised exercise without 23 manipulation; and low dose home exercise with advice. Results suggested that high dose 24 supervised exercise, with or without manipulation, is more effective than low dose home 25 exercise with advice. 26

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Gross et al. (2015) updated a 2010 Cochrane review to assess the effects of manipulation 28 or mobilization alone compared with those of an inactive control or another active 29 treatment on pain, function, disability, patient satisfaction, quality of life and global 30 perceived effect in adults experiencing neck pain with or without radicular symptoms and 31 cervicogenic headache (CGH) at immediate- to long-term follow-up. Authors included 51 32 trials (2920 participants, 18 trials of manipulation/mobilization versus control; 34 trials of 33 manipulation/mobilization versus another treatment, 1 trial had two comparisons). Authors 34 suggest that manipulation and mobilization present similar results for every outcome at 35 immediate/short/intermediate-term follow-up. Multiple cervical manipulation sessions 36 may provide better pain relief and functional improvement than certain medications at 37 immediate/intermediate/long-term follow-up. Since the risk of rare but serious adverse 38 events for manipulation exists, further high-quality research focusing on mobilization and 39 40 comparing mobilization or manipulation versus other treatment options is needed to guide clinicians in their optimal treatment choices. 41

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1 Safety

The potential risk of a major complication due to spinal manipulation is rare. Cassidy, et al. (2008) conducted a nine-year inception cohort study with 100 million patient-years of data. They found no excess risk of chiropractic care over medical care for stroke. They concluded that the most likely explanation is that stroke patients may seek care from chiropractors and medical doctors for headache caused by a stroke prodrome in progress.

7

More common complications are transient local muscle and/or joint soreness (Senstad, et 8 al., 1997; Hurwitz, et al., 2005; Carlesso et al., 2010; Paanalahti et al., 2013; Maiers et al., 9 2015). This is in sharp contrast to the reported risks associated with medication in general 10 where 220,000 deaths are reported each year or the significant risks associated with 11 medications commonly used in the management of spinal pain. It has been reported that 12 there may be as many as 10,000 to 20,000 fatalities (Lazarou, et al., 1998; Weingart, et al., 13 2000) as well as multiple organ systems adversely affected by the commonly used NSAIDS 14 (Carson & Willett, 1993; Wolfe, et al., 1999). COX-2 inhibitors (Bombardier, et al., 2000), 15 as well as the relatively benign analgesic acetaminophen, (Whitcomb & Block, 1994) have 16 also been associated with serious GI, cardiovascular, and hepatic problems at rates that are 17 orders of magnitude greater than complications due to spinal manipulation. Dabbs and 18 Lauretti (1995) estimated the risk of mortality is 400 times greater for NSAIDs than for 19 manipulation in the treatment of neck pain. Rubenstein, et al. (2007) concluded that the 20 benefits of chiropractic care outweigh the risks for the treatment of neck pain in a multi-21 center cohort study. A more detailed discussion including contraindications to 22 manipulation may be found in Bronfort, et al. (2008). 23

25 Conclusion

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41 42 A) Findings include:

- 1) Spinal manipulation in combination with exercise is superior to usual medical care for nonspecific, chronic neck pain.
 - 2) Spinal manipulation is similar in effect to high tech or high dose supervised therapeutic exercise for chronic neck pain.
 - 3) Manipulation in combination with exercise is recommended for non-acute neck pain.
 - 4) The evidence supporting spinal manipulation for acute neck pain is inconclusive but favorable.
- B) The preponderance of evidence supports the use of spinal manipulation for the
 treatment of neck pain:
 - 1) A trial of spinal manipulation is recommended for acute neck pain.
 - 2) Spinal manipulation in combination with exercise is recommended for chronic neck pain.
 - 3) Spinal manipulation in combination with exercise has both short-term and long-term benefit.

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4) Thoracic spine manipulation has a therapeutic benefit for some patients with 1 neck pain. Thoracic spine manipulation alone or in combination with other 2 interventions is a suitable intervention to try in the treatment of non-specific 3 neck pain. 4 5 C) Preventive and maintenance care with spinal manipulation have yet to be justified. 6 7 D) Severe adverse events are extremely rare. Most complications are mild and of short 8 9 duration. 10 11 References Aker PD, Gross AR, Goldsmith CH, Peloso P. Conservative management of mechanical 12 neck pain: systematic overview and meta-analysis. BMJ 1996;313:1291-6. 13 14 Aoyagi M, Mani R, Jayamoorthy J, Tumilty S. Determining the level of evidence for the 15 effectiveness of spinal manipulation in upper limb pain: A systematic review and meta-16 17 analysis. Man Ther. 2014 Nov 15. pii: S1356-689X(14)00224-0. 18 Arkuszewski J. Joint blockage: a disease, a syndrome, or a sign. Man Med 1988;3:132-4. 19 20 Astin JA. Why patients use alternative medicine. JAMA 1998;279:1548-53. 21 22 Black N. Why we need observational studies to evaluate the effectiveness of health care. 23 BMJ 1996;312:1215-8. 24 25 26 Boal RW, Gillette RG. Central neuronal plasticity, low back pain and spinal manipulative therapy. J Manipulative Physiol Ther 2004;27:314-26. 27 28 29 Bogduk N, Jull G. The theoretical pathology of acute locked back: a basis for manipulative therapy. Man Med 1985;23:77-81. 30 31 Bogduk N. The anatomical basis for cervicogenic headache. J Manipulative Physiol Ther 32 33 1992;15:67-9. 34 Bolton PS. Reflex effects of vertebral subluxations: the peripheral nervous system. an 35 update. J Manipulative Physiol Ther 2000;23:101-3. 36 37 Bombardier C, Laine L, Reicin A, Shapiro D, Burgos-Vargas R, Davis B, Day RFMB, 38 Hawkey CJ, Hochber MC, Kvien TK, Schnitzer TJ. Comparison of upper 39 gastrointestinal toxicity of rofecoxib and naproxen in patients with rheumatoid 40 41

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