ICER Chronic Low Back and Neck Pain Draft Scoping Document Open Input Period Commentary from United States Bone and Joint Initiative www.usbji.org April 25, 2017

Dear Sirs,

We, the United States Bone and Joint Initiative (USBJI), offer the following commentary regarding the ICER Chronic Low Back and Neck Pain Draft Scoping Document:

On page 1 you mention that 'several stakeholders' were contacted regarding establishing a research direction, yet to the best of our knowledge the American Physical Therapy Association, the American Chiropractic Association, the American Academy of Physical Medicine and Rehabilitation, the American Osteopathic Association were not contacted, yet all 3 groups have substantial expertise to share regarding chronic back and neck pain. We would appreciate more full disclosure regarding the stakeholders contacted.

On page 1, you refer to physical therapy, seemingly as a generic modality as it is included with exercise therapy and manipulation, when in fact physical therapy is a profession that utilizes many different interventions. As recommended by Alan Jette, PT, PhD, "imprecise use of language in labeling an intervention as 'physiotherapy' and 'occupational therapy' is not unusual; rather it represents an unfortunate norm in the scientific literature." 1

On page 1 you mention that different therapies may be 'complementary' in their effects, and we would encourage your review include all those papers which look at the complementary/additive effects of different therapies.

On page 2 you mention that 'subgrouping' will be utilized in addressing effects of different treatments and we would ask that you spend sufficient time looking at subgroupings/classification models for back and neck pain. Chronic back pain and/or chronic neck pain may be much too heterogeneous a grouping to provide meaningful information. When a group is heterogeneous treatment effects can be 'washed out.'

In the same vein, by defining chronic back/neck pain as pain lasting 12 weeks you are really capturing 'chronic pain syndrome' which may be a psychosocial condition rather than a physical/physiological cause such as spinal stenosis with neurogenic claudication which may last greater than 12 weeks; therefore perhaps classifying the chronic back and neck pain as 'having no other identifiable cause' may prove valuable. Perhaps a better title for this study might be "cognitive and mind-body therapies for chronic pain: effectiveness and value."

As you are looking at 'mind-body' approaches, we would recommend that you focus on studies that have incorporated tools to address psychosocial overlay, such as the StarTBack tool from Keele University. 2

As you will be looking at Cognitive Behavioral Therapy and Mindfulness, we would ask that you consider looking at studies that have contextualized the principles of CBT and Mindfulness into care plans without specifically providing CBT and Mindfulness as stand alone therapies.

As you include comparative effectiveness research, we suggest that you specifically define what 'usual care' consists of.

As the therapies you will be focusing upon are often not covered by insurance, we suggest you incorporate specific strategies to analyze 'out-of-pocket expenditures.

We understand you will be relying on the recently published ACP guidelines for back pain and we would advise against generalizing the results for back pain to chronic neck pain.

We would like to know which specific outcome measures you will be utilizing to determine pain, function, etc.

We strongly recommend you include information from The Bone and Joint Decade Task Force on Neck Pain and Associated Disorders, lead author S. Haldeman, MD, PhD, DC. 3 Please define how the results of this study are proposed to be utilized and by whom.

Jette AM. Language Matters. Phys Ther 2016; 96(6) 754-55.

Foster NE, et al. Effect of stratified care for low back pain in family practice (IMPaCT Back): a prospective population based sequential comparison. Ann Fam Med 2014; 12(2): 102-111. Haldeman, S, et al. The Bone and Joint Decade 2000 – 2010 Task Force on Neck Pain and Its Associated Disorders. Eur Spine J 2008; 17(supplement): S5-S7.

We look forward to reviewing your report when completed and offering our comments again.

Sincerely,

John

John M Ventura, DC Board member, United States Bone and Joint Initiative www.usbji.org

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April 28, 2017

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SUBJECT: ICER Scoping Document on Certain Non-pharmacologic Interventions for

Chronic Low Back and Neck Pain

Dear Colleagues:

The American Association of Neurological Surgeons (AANS), Congress of Neurological Surgeons (CNS) and the AANS/CNS Joint Section on the Disorders of the Spine and Peripheral Nerves (AANS/CNS DSPN) appreciate the opportunity to review the scoping document prepared by the Institute for Clinical and Economic Review (ICER). This paper is intended to inform the California Technology Assessment Forum's (CTAF) consideration of coverage policy for certain non-pharmacologic interventions for chronic low back and neck pain.

The scoping document reports in the background section the estimated costs of back and neck pain in the United States was \$88 billion in 2013. The report further states that the costs for the management of these entities have increased faster than any other group of diagnoses (from 30.4 billion in 1996 to 87.6 billion in 2013). We are concerned that there is no stratification of the costs associated with the various therapies — surgical, injection therapy, physical therapy, etc. We believe that it is essential to identify that the increase in costs is not related to surgical intervention, but rather various nonoperative forms of intervention. ¹

It is evident from the analytical framework used to assess the different therapies that the primary focus is to examine acupuncture, cognitive behavioral therapy, mindfulness, yoga and Tai Chi. The intent of the study is to compare each of these modalities to each other and the "usual care." We would ask further clarity of the definition of "usual care" and whether or not that will include surgical intervention. In conjunction with that question is further clarity regarding the patient population. What patients will be excluded from this study? For instance, a patient with chronic neck pain in the context of progressive myelopathy from advanced cervical spondylosis would benefit little from mindfulness or Tai Chi and benefit most from decompression of their spinal cord. From our review of the scoping document, it is not apparent how patients with chronic pain with a structural element to their pain such as scoliosis, spondylolisthesis, metastatic or primary neoplastic disease will be identified or handled. The literature has demonstrated the cost benefit of timely intervention in these patients. A,5,6,7,8

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Neurosurgery Comments on ICER Scoping Document on Certain Non-pharmacologic Interventions for Chronic Low Back and Neck Pain April 28, 2017 Page 1 of 3

The AANS, CNS and AANS/CNS DSPN believe that pain in and of itself is not an indication for surgical intervention and that there may be a role for cognitive and mind-body therapy for a number of patients with chronic neck and low back pain. However, we would like to emphasize the importance of exhaustive diagnostic imaging and comprehensive neurological assessment to identify those individuals who would benefit most from timely surgical intervention as opposed to non-operative measures, regardless of modality.

We appreciate the ability to share our comments with the ICER and look forward to participating in this process.

Sincerely,

Alex B. Valadka, MD, President

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American Association of Neurological Surgeons

Alan M. Scarrow, MD, President Congress of Neurological Surgeons

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References:

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² Lebl DR, Bono CM. Update on the Diagnosis and Management of Cervical Spondylotic Myelopathy. J Am Acad Orthop Surg. 2015 Nov;23(11):648-60.

Neurosurgery Comments on ICER Scoping Document on Certain Non-pharmacologic Interventions for Chronic Low Back and Neck Pain April 28, 2017 Page 1 of 3

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- ⁵ Weinstein JN1, Tosteson TD, Lurie JD, Tosteson AN, Blood E, Hanscom B, Herkowitz H, Cammisa F, Albert T, Boden SD, Hilibrand A, Goldberg H, Berven S, An H; SPORT Investigators. Surgical versus nonsurgical therapy for lumbar spinal stenosis. N Engl J Med. 2008 Feb 21;358(8):794-810.
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- ⁷ Adogwa O, Parker SL, Davis BJ, Aaronson O, Devin C, Cheng JS, McGirt MJ. Cost-effectiveness of transforaminal lumbar interbody fusion for Grade I degenerative spondylolisthesis. J Neurosurg Spine. 2011 Aug;15(2):138-43.
- ⁸ Klimo P Jr1, Schmidt MH. Surgical management of spinal metastases. Oncologist. 2004;9(2):188-96.

³ Rhee JM, Shamji MF, Erwin MW, Bransford RJ, Yoon T, Smith JS, Kim HJ, Ely CG, Dettori JR, Patel AA, Kalsi-Ryan S. Nonoperative management of cervical myelopathy: a systematic review. Spine 2013; 38(22 Supplement): S55-S67.