<b>Clinical Practice Guideline:</b>	Cervical Pillow and Cervical Supports December 20, 2012	
Date of Implementation: Product:		
	Specialty	
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GUIDELINES	sister (ACII) consider use of comical sillows of one size	
American Specialty Health – Spe	cialty (ASH) considers use of cervical pillows of any size,	
sleep appea improving the quali	ity of sleep, or the management of cervical spine posture	
is considered not medically neces	ssary because scientific literature is inconclusive regarding	
their clinical effectiveness. How	wever, short term use of a cervical pillow for patients	
unresponsive to other established	treatments may be clinically appropriate.	
The use of cervical collars to limit	it range of motion in a post-traumatic, potentially unstable	

spine, is medically necessary. However, use of cervical collars is not medically necessary
 for pain and disability reduction in the absence of spinal instability because the scientific

36 literature is inconclusive regarding the clinical effectiveness.

HCPCS Code	HCPCS Code Description
L0120	Cervical, flexible, nonadjustable, prefabricated, off-the- shelf (foam collar)
L0150	Cervical, semi-rigid, adjustable molded chin cup (plastic collar with mandibular/occipital piece)
L0160	Cervical, semi-rigid, wire frame occipital/mandibular support, prefabricated, off-the-shelf
L0170	Cervical, collar, molded to patient model
L0172	Cervical, collar, semi-rigid thermoplastic foam, two- piece, prefabricated, off-the-shelf
L0174	Cervical, collar, semi-rigid, thermoplastic foam, two piece with thoracic extension, prefabricated, off-the- shelf
L0180	Cervical, multiple post collar, occipital/mandibular supports, adjustable
L0190	Cervical, multiple post collar, occipital/mandibular supports, adjustable cervical bars (SOMI, Guilford, Taylor types)
L0200	Cervical, multiple post collar, occipital/mandibular supports, adjustable cervical bars, and thoracic extension

### 1 HCPCS Codes and Descriptions

2

### 3 **DESCRIPTION/BACKGROUND**

#### 4 Cervical Pillows

Patients are often seeking recommendations about pillows in an effort to decrease cervical 5 and shoulder pain and improve their ability to sleep. Poor sleep is often seen as a significant 6 factor in neck pain leading to a decrease in quality of life, and ability to do their daily 7 activities. Manufacturers and distributors of cervical pillows make many claims about the 8 positive effects of cervical pillows. Cervical pillows are currently marketed claiming to 9 10 provide better support for the cervical spine and improved posture. The claims include the ability to restore and maintain the proper cervical curve. The research that supports the 11 claims for these pillows is lacking. 12 13

The studies available for review focus on either the composition of the pillow, or the shape of the pillow. The composition of the pillows studied included polyester, foam, feather, latex, and water based. One study included a pillow made with sodium sulfate and ceramic fiber (Kawabata & Tokura, 2016). The pillow design factors were described as standard, cradle, cervical, and shoulder. Some of these designs were slightly different as many of the pillows studied were from specific manufacturers and defined their designs differently compared to other manufacturers. One other factor that was not standard throughout the

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1 studies was subject sleeping position. Studies would use either the side lying posture or the

- 2 back lying posture.
- 3

### 4 Cervical Collars/Orthoses

5 Cervical collars have been recommended for conservative care of the cervical spine and to 6 stabilize the spine after injury. They have been prescribed to support the neck and limit 7 motion, to prevent pain, protect spinal instability pre- and post-surgery, and as emergency

- 8 protection post-trauma. They have also been recommended to prevent injury in sports.
- 9

The various types of cervical collars are either soft foam or rigid devices. The soft collars 10 are easy to use and very flexible. Rigid collars provide much more support and are utilized 11 post-fusion, and for unstable fractures. The Philadelphia collar and the Aspen collar are 12 examples of this orthosis. A Miami collar is a variation of the Philadelphia collar and adds 13 more support to the thoracic spine. A cervical thoracic orthosis (CTO) is also used to 14 stabilize the upper cervical vertebrae and is known as a sternal occipital mandibular 15 immobilizer (SOMI). There is a group of cervical collars that have been developed for 16 football players that are made of closed cell polystyrene foam and padding. These collars 17 include the Cowboy collar, Bullock collar, Kerr collar, and the A-force neck collar. 18

19

# 20 EVIDENCE REVIEW

## 21 Cervical Pillow

### 22 Shape and Size

Lavin et al. (1997) compared three pillows and the effect on pain intensity, pain relief, 23 quality of sleep, disability, and overall satisfaction. Twenty-one male and 20 female 24 subjects with chronic neck pain evaluated the participants' usual pillow, a roll pillow, and 25 a water-based pillow. Outcome measures were the visual analog scale (VAS), Sleep 26 Questionnaire, Sickness Impact Profile (SIP), and a satisfaction scale. Length of the study 27 was 5 weeks. They found the water-based pillow was associated with reduced morning 28 pain intensity, increased pain relief, and improved quality of sleep. Duration of sleep was 29 significantly shorter for the roll pillow. SIP findings showed a significant advantage for the 30 water-based pillow. Six of the 41 subjects dropped out from the study. Ten of the remaining 31 subjects had severe discomfort with the roll pillow and stopped using it, without any 32 33 mention of which pillow they substituted at that time. This study had no washout period and could not account for an accumulative effect. 34

35

Hagino et al. (1998) compared a roll-shaped cervical pillow, the Align-Right cervical pillow (ARCP), to the participants' usual pillow in regard to neck pain severity. Both morning and evening neck pain were evaluated using the visual analog scale (VAS). A secondary outcome was use of pain medication. Twenty-eight subjects with chronic neck pain were evaluated over a 4-week period. There were statistically significant decreases in neck/shoulder pain severity suggesting that the ARCP might be an effective option in decreasing neck pain. There was not a significant reduction in pain medication usage. This

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1 was a pre/post intervention study and would need further clinical trials. It is notable that 2 two participants dropped out of the study because of the pain caused by the ARCP.

3

Ambrogio et al. (1998) evaluated three different pillows with 35 fibromyalgia patients 4 (FMS). The pillows were a cervical pillow (Shape of Sleep) with a more rigid support, a 5 standard pillow with two neck ruffs, and a standard pillow. Outcome measures included 6 the visual analog scale (VAS) and the Fibromyalgia Impact Ouestionnaire (FIO). Most of 7 the participants (62.9%) preferred the Shape of Sleep pillow. Although there was a trend 8 towards improvement in the VAS and FIQ, it was not statistically significant. This indicates 9 that the design of a pillow may provide more comfort for a patient but that does not 10 11 necessarily translate to an improvement in health outcomes.

12

Kushida et al. (1999) evaluated the effects of a custom designed cervical pillow on 12 13 subjects with Obstructive Sleep Apnea Syndrome (OSAS). The subjects were comparing 14 their usual pillow against the cervical pillow. The intervention period was 1 week. 15 Outcomes were subjective questionnaires, videotape of head and body position, and 16 recording of breathing parameters during sleep. There was a significant improvement in 17 the respiratory disturbance index for the 3 subjects with mild OSAS. The 4 subjects with 18 moderate OSAS showed no improvement. The 5 subjects with severe OSAS showed slight 19 20 improvement in some of the abnormal respiratory events during the sleep period.

21

Palazzi et al. (1999) compared the effect of a cervical pillow (Sleep Easy Pillow) with a 22 standard pillow on 15 patients with myogenic cranio-cervical mandibular dysfunction. 23 Electromyography (EMG) activity of the sternocleidomastoid muscles was recorded in the 24 supine or side lying position (dependent on the subject's normal habit). In the side lying 25 position, there was a significantly higher EMG reading in the contralateral 26 sternocleidomastoid muscle for both pillows. This is one of the few studies that did not rely 27 on the subjects filling out questionnaires or surveys. EMG activity may be a way of helping 28 to design a pillow that provides more support. There is also the question of whether 29 symmetrical EMG readings would lead to improved sleep or a decrease in 30 cervical/shoulder symptoms. 31

32

Santander et al. (2000) compared the effect of head and neck inclination on bilateral sternocleidomastoid EMG activity in asymptomatic subjects and Congenital Muscular Dystrophy (CMD) patients. Subjects were tested with head, neck and body aligned; head and neck upwardly inclined with a thick pillow; and head and neck downwardly inclined with a thin pillow. There was a significantly higher contralateral EMG activity and a more asymmetric activity in the CMD patients. This could indicate that different pillows might be needed for an individual depending on presence of symptoms.

40

Erfanian et al. (2004) conducted a randomized controlled trial to examine the effects of a
 semi-customized cervical pillow on 36 adults with chronic neck pain (with and without

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headache). They used an experimental pillow with foam quadrants that allowed the subject to choose between four heights. The outcome measures were a mail-in daily pan diary and the Canadian Memorial Chiropractic (CMCC) Neck Disability Index (NDI). The intervention period was 4 weeks. There was a statistically significant decrease in reported pain scores and the NDI in the experimental group. Notable is the fact that 11 of the original 36 subjects dropped-out of this study for varying reasons. The researchers also noted that they were not sure if the subjects were using the pillow as prescribed.

8

9 Shields et al. (2006) did a systematic review to see if cervical pillows were effective in 10 decreasing neck pain. The authors looked for articles where the participants had neck pain 11 and there were outcome measures for the assessment of pain. Articles involving any 12 concurrent therapies were excluded. There were 127 articles identified but only 5 articles 13 of low quality met the selection criteria. There was not enough evidence at that time to 14 state that cervical pillows could reduce neck pain.

15

Liu et al. (2011) examined the relationship between pillow shape design and subjective 16 comfort level for asymptomatic patients. They used subjects who only preferred to lay flat 17 while sleeping. They used 8 pillows which were different combinations of design such as 18 standard, cradle, cervical, and shoulder. Outcome measurement was the subjective opinion 19 20 of comfort level, and preferred height and angle of the pillow. The results indicate that subjects preferred redesigned pillows that were combinations of design, rather than a 21 specific design. One limitation is that some subjects reported different comfort levels for 22 the same pillow during the comparison. Also noted is that each subject only laid on a pillow 23 for one minute before comparing comfort levels. 24

25

Helewa et al. (2007) examined the effects of therapeutic exercise in combination with 26 pillows on patients with chronic neck pain. One hundred and fifty-one subjects were 27 divided into four groups: group 1 was the control; group 2 was the cervical pillow and 28 placebo; group 3 was active neck exercises and placebo; and group 4 was the combination 29 of the cervical pillow and active neck exercises. The primary outcome assessment tool was 30 the Northwick Park Neck Pain Questionnaire (NPQ). The exercise group (group 3) and the 31 cervical pillow group (group 2) were not statistically different from the control group 32 33 (group 1). The combination of exercise and the cervical pillow (group 4) were statistically significant and supported clinical use. Jamal et al. (2016) reanalyzed data from Helewa et 34 al. (2007) to further characterize the effects of postural exercises and neck support pillows 35 on neck pain. Results demonstrated that postural exercises significantly decreased NPQ 36 scores at  $\geq 3$  weeks, and the use of a neck support pillow significantly decreased NPQ 37 scores at  $\geq 12$  weeks. Authors conclude that these interventions could be beneficial in 38 39 reducing neck pain symptoms.

- 40
- Kiatkulanusorn et al. (2021) investigated neck and back muscle activity in individuals with
   and without forward head posture (FHP) during a maintained side-sleeping position by

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incorporating various pillow designs. Thirty-four participants were enrolled. The muscle 1 activity was investigated via surface electromyography during the use of three trial pillows: 2 orthopedic pillow, hollow pillow, and Thai neck support pillow. For all three pillow 3 designs, the FHP group demonstrated significantly greater middle-lower trapezius muscle 4 activity than the normal head posture group. Sternocleidomastoid and upper trapezius (UT) 5 muscle activity were similar between the two groups. Only UT muscle activity was affected 6 by variations in pillow design. In the normal group, no difference was observed in the 7 muscle activity between all three pillows (p > 0.05). Authors concluded that the ability to 8 appropriately modify a pillow configuration without creating undesired muscle activation 9 was limited to those exhibiting FHP. Therefore, specially designed pillows or mattresses 10 11 should be investigated in terms of their relevance to muscle fatigue and potential musculoskeletal pain in FHP patients. 12

- 13
- 14 Composition

Gordon et al. (2010) examined whether pillows of different composition produce different 15 types and frequencies of waking symptoms in asymptomatic subjects. The pillows were 16 polyester, foam regular, foam contour, feather, and latex. Each pillow was tried for a week 17 and the subjects' own pillow was the control. There was a washout period for each pillow. 18 Side sleepers only were the subjects. Outcome measures were the recorded reports of 19 20 waking cervical stiffness, headache, and scapular/arm pain. Results of the study showed that the feather pillow provided the highest frequency of waking symptoms and produced 21 the greatest number of dropouts during the trial. There was no significant difference 22 between the foam contour pillow and the foam regular pillow. The latex pillow seemed to 23 perform best. The authors felt that a study examining the effects of a latex pillow on 24 symptomatic patients would be appropriate. 25

26

27 Gordon et al. (2011) examined the effect of pillow shape and composition on the slope of cervico-thoracic spine segments in a side lying position. Ninety-five subjects who were not 28 receiving any treatment for neck symptoms were included. The trial pillows were regular 29 shaped polyester, foam, feather, latex, and a contour shaped foam. Reflective markers were 30 placed on the external occipital protuberance (EOP), C2, C4, C7, and T3. Each subject 31 rested on the pillow for 10 minutes and digital images were recorded. The slope of each 32 33 spinal segment was calculated from these images. At zero and 10 minutes, EOP-C2, C2-C4, C4-C7, C7-T3 segmental slopes were significantly different across all pillows, 34 although the slope changes were small. The C2-C4 segment seems to be most sensitive to 35 change. Foam regular, foam contour, and latex pillows support each segment in a similar 36 37 manner, as do the polyester and feather pillows.

38

Vanti et al. (2019) investigated the effectiveness of a "spring pillow" for adults with chronic nonspecific neck pain. Authors evaluated the effectiveness of using a pillow made from viscoelastic polyurethane and 60 independent springs compared with an educational intervention in individuals with chronic nonspecific neck pain in a randomized controlled

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trial with crossover study design. Participants (n=64) were randomly assigned to two 1 groups. One group used the spring pillow for 4 weeks, and the other group followed 2 educational advice for 4 weeks while continuing to use their own pillows. After 4 weeks 3 of treatment and 4 weeks of washout, groups were crossed over. Pain perceived in the neck, 4 thoracic, and shoulder areas and headache were the primary outcome measures. In addition, 5 disability, sleep quality, subjective improvement, and pillow comfort were assessed. 6 Measures were captured at pretreatment, after 4 weeks, after the 4-week washout period, 7 and 4 weeks after crossover. Results reported that treatment with the spring pillow 8 appeared to reduce neck pain, thoracic pain, and headache. Reductions in shoulder pain 9 were not statistically significant between groups. Neither the crossover sequence nor the 10 11 period (first vs second intervention administration) significantly affected the results.

12

Authors noted that education may not have been the best comparator for the spring pillow; 13 drug consumption, actual pillow use, and the implementation of the educational 14 suggestions as prescribed were not controlled and are limitations to the findings. Authors 15 concluded that use of the spring pillow in this study was more effective than an educational 16 intervention for improving cervical, thoracic, and head pain. Whether a spring pillow is 17 more effective than other ergonomic pillows remains to be tested. Background: In people 18 without cervical pathologies, changing to a latex or polyester pillow is reported to decrease 19 20 waking cervical symptoms. Whether this also occurs for people with spinal degeneration in the neck is unknown. 21

22

Chun-Yiu et al. (2021) completed a systematic review and meta-analysis to identify clinical 23 trials assessing the effect of different types of pillows on neck pain, waking symptoms, 24 neck disability, sleep quality, and spinal alignment. Thirty-five articles fulfilled the 25 inclusion criteria of the study. There were nine high-quality studies involving 555 26 participants. The meta-analysis revealed significant differences favoring the use of rubber 27 pillows to reduce neck pain. Moreover, waking pain and neck disability were reduced while 28 the satisfaction rate was enhanced with pillow use. Pillow designs did not influence sleep 29 quality in patients with chronic neck pain. Authors concluded that the use of spring and 30 rubber pillows are effective in reducing neck pain, waking symptoms, and disability and 31 enhancing pillow satisfaction in patients with chronic neck pain. Moreover, there may be 32 33 no change in the alignment of the cervical spine in the side-lying position, regardless of the use of rubber or feather pillows. Rather, the cervical alignment may be significantly 34 impacted by the shape and height of the pillow. 35

36

#### 37 <u>Thermoregulatory Responses</u>

Kawabata and Tokura (1996) compared thermoregulatory responses for two types of pillows. Heat loss from the head to the surrounding air during sleep might be relevant to sleep depth (Kawabata et al., 1995). The thermoregulatory responses of a pillow with a cooling medium of sodium sulfate and ceramic fiber were compared to a polyester pillow.

42 Five female students volunteered for this study. Each subject slept 2 nights on each pillow.

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1 The outcome measures were a questionnaire that was filled out after each night slept, and 2 rectal, forehead, palm, and thigh skin temperatures. Heart rate was also measured. It was

concluded that the ceramic fiber pillow produced a slight cooling of the head that wasassociated with a deeper, more comfortable sleep.

5

6 One of the claims of the very commonly recommended Sobakawa pillow is the ability to 7 keep the head cool. There is not one citation that references the Sobakawa pillow as being 8 used in a research study.

9

Cervical pillows are being advertised and marketed with a number of different claims.
These pillows supposedly improve cervical support and help preserve the normal cervical
curve. One can get a more restful sleep and wake up with fewer symptoms in the morning.
These symptoms include stiffness, headaches, and neck/shoulder/arm pain.

14

The lack of research and low quality of many of these studies do not support any of these 15 claims. Many of the studies did not use an adequate number of subjects. Intervention 16 periods in these studies tend to be relatively short so extrapolation cannot be made to long 17 term effects. There seems to be some evidence that latex pillows might provide some relief 18 in cervical symptoms. There is also some indication that custom designed pillows may 19 20 provide relief of morning pain and decrease stiffness. Pillows that cool the head may also provide a more restful and comfortable sleep. Some of the studies indicate that it may be 21 wise to avoid feather pillows. In any case, it is clear that more randomized controlled 22 studies are needed. 23

24

# 25 Cervical Collar

### 26 Restriction of Range of Motion

Gavin et al. (2003) evaluated cervical flexion and extension, when comparing cervical 27 collars to cervical thoracic orthoses (CTO). Aspen and Miami J models were used as the 28 cervical collars. Aspen 2-post and 4-post models were the CTOs used. Twenty normal 29 subjects were studied. Gross sagittal motion of the head was measured at the same time as 30 cervical intervertebral motion was measured using videofluoroscopy. Surface 31 electromyographic signal data was also measured to compare the effort used by the subjects 32 33 while in the different orthoses. Each orthosis significantly reduced gross and intervertebral motion in flexion and extension. There was no statistical significance between the Miami 34 J and Aspen collars in reducing motion except at the C5-6 levels. As half of the cervical 35 fractures seen in emergency departments are at the C6-7 level, this can be an important 36 difference. The Aspen 2-post and 4-post models performed similarly in flexion, but the 4-37 post model provided significantly more extension restriction. 38

- 39
- Sandler et al. (1996) compared flexion-extension, axial rotation, and lateral flexion
   measurements in 5 different cervical orthoses. Five subjects were measured both actively
   and passively. All of the collars restricted movement to some extent. As would be expected,

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the collars ranked from least restrictive to most restrictive went from soft foam to rigid. The order was soft, Philadelphia, Philadelphia with extension, and sterno-occipital mandibular immobilizer brace. None of these braces were able to restrict motion completely. The minimum limitations were 19 degrees in flexion-extension, 46 degrees in rotation, and 45 degrees in lateral flexion. All of the measurements were for gross motion and there was no differentiation for specific spinal segments.

7

Miller et al. (2010) compared soft and rigid collars for restricting cervical motion during 8 15 activities of daily living (ADLs). An electrogoniometer device was used to measure 9 range of motion (ROM) of 10 subjects during the ADLs. Active ROM as well as functional 10 11 ROM was measured. Range of motion measurements were repeated after the application of the soft collar, and then the rigid orthosis. The rigid collar significantly restricted ROM 12 in both the sagittal and axial planes, but not in lateral flexion. The rigid collar was not 13 statistically different in 13 of the 15 ADLs when compared to the soft collar. Greater 14 motion in the rigid orthosis was noted when backing up a car and sitting from a standing 15 position. Although there was a difference in full active ROM between the orthoses, this did 16 not translate to functional activity. In many of the ADLs, full cervical ROM is not used. 17 Rigid orthoses may not be necessary in some patients, and soft collars, which subjectively 18 seem more comfortable, may restrict activity enough for ADLs. 19

20

Whitworth et al. (2011) compared cervical motion between a soft collar and a rigid brace 21 in 50 healthy subjects. Subjects ranged in age from 22 to 67 years. Active flexion, 22 extension, right and left lateral flexion, and right and left rotation was measured using a 23 cervical range of motion goniometer. Both the soft collar and brace reduced cervical 24 motion compared to no collar, but the rigid brace was significantly more effective at 25 reducing motion. The soft collar reduced motion on average by 17.4%, and the rigid brace 26 reduced motion by 62.9%. The effect of the collar and brace was not affected by age. The 27 choice of a collar or brace might depend on the cervical condition that is being treated. The 28 lesser reduction may be the better choice in less severe cervical strains. 29

30

31 Askins and Eismont (1997) evaluated flexion, extension, lateral flexion, and rotation in five different rigid cervical orthoses. Ten men and 10 women were evaluated in the 32 33 Philadelphia collar, the Aspen, the Stifneck, the Miami J, and the NecLoc. Rotation was measured using a compass goniometer, but all other measurements were done from x-rays 34 of the cervical spine. All orthoses demonstrated restriction of cervical movement, but the 35 NecLoc had a statistically significant advantage in restricting movement. Measuring 36 37 cervical movement from radiographs may be a problem in this study. Future research projects should take into account muscle activity that could be altered in an asymptomatic 38 39 subject in a rigid brace.

40

James et al. (2004) looked at the cervical spine ROM that occurred during the application of four rigid cervical collars, the time of application and the amount of active ROM

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available after application. The authors noted that 25% of cervical spine injuries occur after 1 the initial injury. They tested the NecLoc (NL), StifNeck (SN), StifNeck Select (SNS) and 2 the Rapid Form Vacuum Immobilizer (VI). Seventeen certified athletic trainers applied the 3 collars to 2 male models. A repeated-measure design was used. Data was collected using 4 an electromagnetic tracking device. The results show that although there was no significant 5 difference for peak angular displacement (PAD) between collars, PAD did occur which 6 could cause secondary injury. The authors noted that the ideal cervical brace would be easy 7 and quick to apply, have less movement during application, and provide the most restriction 8 during active range of motion. The authors concluded that the SN and SNS were the better 9 options of the models they tested. Holla et al. (2016) reviewed the ability of various types 10 11 of external immobilizers to restrict cervical spine movement. Results demonstrated that the ability to reduce the range of motion by soft collars was poor in all directions. The ability 12 of cervico-high thoracic devices was moderate for flexion/extension but poor for lateral 13 bending and rotation. The ability of cervico-low thoracic devices to restrict 14 flexion/extension and rotation was moderate, while their ability to restrict lateral bending 15 was poor. All cranio-thoracic devices for non-ambulatory patients restricted cervical spine 16 movement substantial in all directions. The ability of vests with non-invasive skull fixation 17 was substantial in all directions. No studies with healthy adults were identified with respect 18 to cranial traction and halo vests with skull pins and their ability to restrict cervical 19 20 movement. Authors concluded that soft collars have a poor ability to reduce mobility of the cervical spine. Cervico-high thoracic devices primarily reduce flexion and extension, 21 but they reduce lateral bending and rotation to a lesser degree. Cervico-low thoracic 22 devices restrict lateral bending to the same extent as cervico-high thoracic devices, but are 23 considerably more effective at restricting flexion, extension, and rotation. Finally, cranio-24 thoracic devices nearly fully restrict movement of the cervical spine. 25

26

27 Oshlag et al. (2020) authored a general article on neck injuries. In athletes, injuries are most common in contact sports, and occur with direct axial loading with a forward-flexed neck. 28 Soft tissue and peripheral nerve injuries are typically minor and self-limiting, with 29 excellent recovery potential and return to activities based on symptoms. Concern for 30 devastating spinal cord injuries has led to routine immobilization using spine boards and 31 hard cervical collars. They conclude that this approach may provide more harm than benefit 32 33 when applied universally, and a more commonsense protocol can be used to better address potential neck injuries. See Kane and Braithwaite (2021) for a summary of cervical collars 34 and spinal motion restriction. 35

- 36
- 37 Whiplash Injuries

Kongsted et al. (2007) compared the effect of three different interventions in subjects who had a whiplash injury. Patients were recruited within 10 days to be in one of the following three intervention groups. The first group was immobilization of the cervical spine in a rigid collar followed by active mobilization. The second group advised to "act as usual".

42 The third group had an active mobilization program of manual care and exercise. Outcome

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assessment was based in terms of headache, neck pain intensity, disability, and work capability. Follow-up was done at 3-, 6-, and 12-months post-injury. At the one-year follow-up, 48% of the patients reported considerable neck pain, and 53% disability independent of their assigned intervention group.

5

Dehner et al. (2006) compared the relative benefits of 2 versus 10 days of soft collar 6 immobilization after acute whiplash injury. Seventy patients with Quebec Task Force 7 (QTF) grade II whiplash injuries were randomized to either the two day or ten-day 8 immobilization with a soft collar group. Patients were assigned within 24 hours of the 9 whiplash injury. All other treatments were equal. All patients received non-steroidal anti-10 11 inflammatory drugs (NSAIDs) and started physiotherapy after 7 days, 2-3 times a week. Outcome measures were pain and disability scores, and ROM using a goniometer. At both 12 2 months and 6 months there was no difference in the two groups in terms of pain, ROM, 13 14 or disability.

15

Rosenfeld et al. (2006) compared costs and results in two different intervention groups for patients who had whiplash after an automobile accident. One group used exercise and early mobilization. The other group was a standard recommendation for rest and short-term immobilization in a cervical collar. This was a randomized controlled trial. Using a costconsequence analysis, the authors concluded that the exercise and early mobilization group were statistically better in reducing pain and reducing sick leave. The exercise and mobilization group were more effective and less costly than the standard intervention.

23

24 Ricciardi et al. (2019) performed a systematic review of the randomized control trials (RCTs) and a pooled analysis in order to investigate the role of the non-rigid cervical 25 collars (nRCC) for pain management, scored through the visual analogue scale (VAS) and 26 the ROM, by comparing the use of a nRCC (for 1-2 weeks) with a non-immobilization 27 protocols, regardless of the association with physical therapy (PT). Only patients with 28 whiplash-associated disorders (WAD) grade I-II were included. A total of 141 papers were 29 reviewed; 6 of them matched the inclusion criteria and were admitted to the final study. 30 Pooled analysis showed that nRCC does not improve the outcome in terms of VAS score 31 and ROM trends along the follow-up. Additionally, VAS and ROM trends seem to further 32 33 improve at long-term follow-up in non-immobilization associated with PT group. Authors concluded that this analysis shows the absence of an advantage of the immobilization 34 protocol with a nRCC after WAD. In contrast, non-immobilization protocols show an 35 overall better trend of pain relief and neck mobility recovery, regardless of the association 36 37 of PT.

38

Christensen et al. (2021) performed a systemic review to investigate the effectiveness of soft-collar use on pain and disability in WAD. Four RCTs (n = 409) of fair-good quality (PEDro-scores) were included. Three used a soft collar in addition to other conservative

42 treatment; one study compared soft-collar use to act-as-usual. All studies found that an

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active or act-as-usual approach was more effective in reducing pain intensity compared to 1 soft-collar use, confirmed by meta-analysis (2 RCTs with data: SMD of -0.80 (-1.20, -2 0.41)). No studies reported disability outcomes while contrasting results were found 3 between groups regarding total cervical range of motion (2 RCTs with data: SMD of 0.16 4 (-0.21, 0.54)) or rotation (two RCTs with data: SMD of 0.54 (-0.19, 1.27)). Overall quality 5 of the evidence was low to very low. The authors concluded that all four RCTs favored an 6 active approach/act-as-usual over soft-collar treatment. However, due to methodological 7 concerns and low certainty of evidence, future studies investigating soft collar use in 8 combination with an active rehabilitation strategy for acute/subacute WAD are needed. 9

10

11 Mourad et al. (2021) investigated the impact of the early use of soft cervical collars on the return to the emergency department (ED), within 3 months of a road traffic collision. 12 Patients in the earlier acute phase of WAD (within 48 h from the trauma) were included; 13 those with serious conditions (WAD IV) were excluded. As an end point, authors 14 considered patients who returned to the ED complaining of WAD symptoms within three 15 months as positive outcome for WAD persistence. 2162 patients were included; of those, 16 85.4% received a soft cervical collar prescription. Further, 8.4% of those with a soft 17 cervical collar prescription, and 2.5% of those without a soft cervical collar returned to the 18 ED within three months. The use of the soft cervical collar was an independent risk factor 19 20 for ED return within three months, with an OR, adjusted for possible clinical confounders, equal to 3.418 (95% CI 1.653-7.069; p < 0.001). After the propensity score matching, 21 25.5% of the patients (n = 25/98) using the soft cervical collar returned to the ED at three 22 months, compared to the 6.1% (n = 6/98) that did not adopt the soft cervical collar. The 23 use of a soft cervical collar was associated with ED return with an OR = 4.314 (95% CI 24 2.066-11.668; p = 0.001). Authors concluded that the positioning of the soft collar in a 25 cohort of patients with acute WAD, following a rear-end car collision, is an independent 26 potential risk factor to the return to the ED. Clinically, the use of the collar is a non-27 recommended practice and seems to be related to an increased risk of delayed recovery. 28 Future primary studies should determine differences between having used or not having 29 used the collar and compare early physical therapy in the ED compared with the utilization 30 of the collar. 31

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### 33 Cervical Radiculopathy

Kuijper et al. (2009) did a randomized controlled trial to see if a cervical collar or 34 physiotherapy was better than a wait-and-see policy for early pain relief in cervical 35 radiculopathy. Two hundred and eight patients who had cervical radiculopathy with 36 symptoms for one month were assigned to one of three groups. Sixty-nine patients were 37 put in a semi-hard cervical collar for 3 weeks and told to rest as much as possible. They 38 39 were weaned off collar use for the next 3 weeks. Seventy patients were assigned to twice weekly physiotherapy and daily home exercises for 6 weeks. Sixty-six patients were 40 assigned to the third group of just waiting. At 6 weeks, cervical collars and physiotherapy 41 decreased neck and arm pain more than the wait group. The semi-hard cervical collars had 42

**CPG 162 Revision 12 – S** Cervical Pillow and Cervical Supports **Revised – July 18, 2024** To CQT for review 06/10/2024 CQT reviewed 06/10/2024 To QIC for review and approval 07/02/2024 QIC reviewed and approved 07/02/2024 To QOC for review and approval 07/18/2024 Page 12 of 17

a greater reduction in neck disability than the wait group. At 6 months, there was no 1 difference between groups for any of the outcome measures. Although both intervention 2 groups reported a decrease in pain, there was no decrease in the use of pain medications. 3 Thoomes et al. (2013) completed a systematic review on the effectiveness of conservative 4 treatment for patients with cervical radiculopathy. Fifteen articles were included that 5 corresponded to 11 studies. Findings suggest there is low-level evidence that a collar is no 6 more effective than physiotherapy at short-term follow-up and very low-level evidence that 7 a collar is no more effective than traction. The authors do conclude that use of a collar and 8 physiotherapy show promising results at short-term follow-up. In the 2017 Neck Pain: 9 Revision of the Clinical Practice Guidelines Linked to the International Classification of 10 11 Functioning, Disability and Health From the Orthopaedic Section of the American Physical Therapy Association, Blanpied et al., states that for patients with acute neck pain with 12 radiating pain, clinicians may provide short term use of a cervical collar. However, this is 13 based on grade C evidence, which is weak. 14

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The Royal Dutch Society for Physical Therapy (KNGF) authored by Bier et al. (2018) 16 issued a clinical practice guideline for physical therapists that addresses the assessment and 17 treatment of patients with nonspecific neck pain, including cervical radiculopathy, in Dutch 18 primary care. Recommendations were based on a review of published systematic reviews. 19 20 The physical therapist is advised not to use dry needling, low-level laser, electrotherapy, ultrasound, traction, and/or a cervical collar. In case of neck pain grade III, the use of a 21 cervical collar for pain reduction may be considered. The advice is to use it sparingly: only 22 for a short period per day and only for a few weeks. 23

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### 25 PRACTITIONER SCOPE AND TRAINING

Practitioners should practice only in the areas in which they are competent based on their education training, and experience. Levels of education, experience, and proficiency may vary among individual practitioners. It is ethically and legally incumbent on a practitioner to determine where they have the knowledge and skills necessary to perform such services.

It is best practice for the practitioner to appropriately render services to a patient only if they are trained, equally skilled, and adequately competent to deliver a service compared to others trained to perform the same procedure. If the service would be most competently delivered by another health care practitioner who has more skill and expert training, it would be best practice to refer the patient to the more expert practitioner.

36

Best practice can be defined as a clinical, scientific, or professional technique, method, or process that is typically evidence-based and consensus driven and is recognized by a majority of professionals in a particular field as more effective at delivering a particular outcome than any other practice (Joint Commission International Accreditation Standards for Hospitals, 2020).

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Depending on the practitioner's scope of practice, training, and experience, a member's 1 condition and/or symptoms during examination or the course of treatment may indicate the 2 need for referral to another practitioner or even emergency care. In such cases it is prudent 3 for the practitioner to refer the member for appropriate co-management (e.g., to their 4 primary care physician) or if immediate emergency care is warranted, to contact 911 as 5 appropriate. See the Managing Medical Emergencies (CPG 159 - S) clinical practice 6 guideline for information. 7 8 REFERENCES 9 Ambrogio N, Cuttiford J, Lineker S, Li L. A comparison of three types of neck support in 10 fibromyalgia patients. Arthritis Care Res. 1998 Oct; 11(5):405-410 11 12 American Medical Association. (current year). Current Procedural Terminology (CPT) 13 Current year (rev. ed.). Chicago: AMA 14 15 American Medical Association (current year). HCPCS Level II. American Medical 16 Association 17 18 Askins V, Eismont FJ. Efficacy of five cervical orthoses in restricting cervical motion. A 19 20 comparison study. Spine 1997 Jun 1; 22(11):1193-8 21 Bier JD, Scholten-Peeters WGM, Staal JB, Pool J, van Tulder MW, Beekman E, Knoop J, 22 Meerhoff G, Verhagen AP. Clinical Practice Guideline for Physical Therapy 23 Assessment and Treatment in Patients With Nonspecific Neck Pain. Phys Ther. 2018 24 Mar 1;98(3):162-171. doi: 10.1093/ptj/pzx118 25 26 Blanpied PR, Gross AR, Elliott JM, Devaney LL, Clewley D, Walton DM, Sparks C, 27 Robertson EK. Neck Pain: Revision 2017. J Orthop Sports Phys Ther. 2017 28 Jul;47(7):A1-A83 29 30 Christensen, S., Rasmussen, M. B., Jespersen, C. L., Sterling, M., & Skou, S. T. (2021). 31 Soft-collar use in rehabilitation of whiplash-associated disorders - A systematic review 32 33 and meta-analysis. *Musculoskeletal* science k practice, 55, 102426. https://doi.org/10.1016/j.msksp.2021.102426 34 35 36 Chun-Yiu JP, Man-Ha ST, Chak-Lun AF. The effects of pillow designs on neck pain, waking symptoms, neck disability, sleep quality and spinal alignment in adults: A 37 systematic review and meta-analysis. Clin Biomech (Bristol, Avon). 2021 38 39 May;85:105353. doi: 10.1016/j.clinbiomech.2021.105353

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